Supreme Court, U.S.
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No. 00-

IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC. and
CIRCA PHARMACEUTICALS, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 21 U.S.C. § 355(j)(2)(A)(v), the provision of the Federal Food, Drug, and Cosmetic Act that requires the labeling of a generic drug to be "the same as" that of the pioneer drug, effectively repeals the Copyright Act.

PARTIES TO THE PROCEEDING

Petitioner is SmithKline Beecham Consumer Healthcare, L.P. Respondents are Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc.

STATEMENT PURSUANT TO RULE 29.6

Pursuant to Rule 29.6 of the Rules of this Court, Petitioner SmithKline Beecham Consumer Healthcare, L.P. certifies that the following publicly held entities are parents of Petitioner and/or own 10% or more of Petitioner's stock:

SmithKline Beecham Corporation
SmithKline Beecham plc

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Petitioner respectfully requests that a writ of certiorari be issued to review the judgment of the United States Court of Appeals for the Second Circuit, entered on April 4, 2000.

OPINIONS BELOW

The opinion and judgment of the Court of Appeals is reported at 211 F.3d 21 (2d Cir. 2000) and is set forth in Appendix ("App.") A hereto. One relevant opinion of the district court is reported at 63 F. Supp. 2d 467 (S.D.N.Y. 1999); the other relevant opinions by the district court are unreported. The district court opinions are set forth in Apps. B, C, and E hereto.

STATEMENT OF JURISDICTION

This Court has jurisdiction to review the judgment of the Court of Appeals by writ of certiorari pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Article 1, Section 8, Clause 8 of the United States Constitution grants Congress the power:

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

Section 102 of the Copyright Act of 1976, 17 U.S.C. § 102 (1999), provides, in pertinent part:

> Copyright protection subsists, in accordance with this title, in original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. . . .

Section 106 of the Copyright Act of 1976, 17 U.S.C. § 106 (1999), provides, in pertinent part:

> Subject to sections 107 through 121, the owner of copyright under this title has the exclusive rights to do and to authorize any of the following:
>
> > (1) to reproduce the copyrighted work in copies or phonorecords. . . .

Section 505(a) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 355(a) (1999), provides:

> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

Section 505(c)(3)(D)(iii) of the FFDCA, 21 U.S.C. § 355(c)(3)(D)(iii) (1999), provides:

> If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

Section 505(j)(2)(A)(v) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(v) (1999), provides, in pertinent part, that an abbreviated new drug application (ANDA) must include:

> information to show that the labeling proposed for the new drug is the same as the labeling

> approved for the listed drug . . . except for changes required because . . . the new drug and the listed drug are produced or distributed by different manufacturers.

21 C.F.R. § 201.66 (1999) is set forth in App. H.

STATEMENT OF THE CASE

Petitioner SmithKline Beecham Consumer Healthcare, L.P. ("SmithKline") challenges a ruling of the Court of Appeals for the Second Circuit which held that the federal statute regulating the approval of generic drug labeling partially repeals the constitutionally-grounded Copyright Act, even though no such intention is embodied in either the statute or its legislative history. The issue arose in a copyright infringement action commenced by SmithKline in the Southern District of New York to enjoin Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. (collectively, "Watson"), a generic drug manufacturer, from infringing the copyrighted booklet ("User's Guide") and audio cassette tape ("Audiotape") that are distributed as behavioral support materials with SmithKline's branded nicotine polacrilex gum, Nicorette® ("Nicorette"). The district court initially granted SmithKline's request for a preliminary injunction and then subsequently changed its mind. The district court's ruling dissolving the preliminary injunction was affirmed by the Second Circuit.

Essentially, the Court of Appeals held that the provision of the Federal Food, Drug, and Cosmetic Act (FFDCA) that requires the labeling proposed for a generic drug to be "the same as" that of the listed (pioneer) drug to which the generic

drug is equiva[illegible]ivalent, mandates the loss of copyright protection for original wo[illegible]l works of authorship. Under the Court of Appeals' ruling, the Fe[illegible]e Food and Drug Administration (FDA) must require generi[illegible]neric drug manufacturers to copy wholesale and verbatim even[illegible]ven the concededly creative, copyrightable aspects of the labelin[illegible]eling of pioneer drugs, including (in this case) illustrations, [illegible]s, the distinctive wording of smoking cessation concepts and t[illegible]nd tips, and fictional support group and relaxation session enactm[illegible]actments on the Audiotape. The Court of Appeals reached this c[illegible]is conclusion notwithstanding the fact that "same as" has *not* be[illegible]*t* been interpreted even by FDA to require identical, verbatim co[illegible] copying of all materials and notwithstanding the absence [illegible]ce of any express congressional directive that copyright pr[illegible] protection in materials submitted by a pioneer drug manufa[illegible]ufacturer for approval be forfeited to generic competitors. [illegible]rs. In fact, the Court of Appeals acknowledged that Congress ne[illegible] never considered the interplay of these two important bo[illegible] bodies of federal law — the FFDCA and the Copyright Ac[illegible] Act — in passing the pertinent provisions of the FFDCA. The[illegible]he Court of Appeals' holding that SmithKline has no valid copy[illegible]opyright infringement claim represents a serious threat to the i[illegible]he integrity of the copyright laws.

By findi[illegible]nding that the FFDCA abrogates and partially repeals the C[illegible]e Copyright Act, the Court of Appeals violated the fundamental [illegible]tal principle of statutory construction that repeals by implicatio[illegible]ation are disfavored where the arguably conflicting statutes can b[illegible]n be harmonized without undermining the purpose of either. In t[illegible]n this case, such harmonization can be effectuated by interpreti[illegible]reting the FFDCA to require that generic drug labeling cont[illegible]ontain the same factual information and concepts as that of the [illegible]he pioneer drug, but that it use different means of expression w[illegible]n where necessary to avoid copyright infringement. Such an inter[illegible]nterpretation of the "same as" requirement would

not undermine the FFDCA's purpose of facilitating the approval of generic drugs; it would permit the copying of material necessary to inform consumers about the medical effects and proper usage of the drug in question. At the same time, it would prevent wholesale abridgements of constitutionally-rooted copyright rights such as that which occurred in this case.[1]

The Court of Appeals' dramatic departure from longstanding principles of statutory construction has implications that reach far beyond the specific issue presented in this case. The proposition that a court can blithely nullify intellectual property rights or any other rights conferred by Congress based on speculation as to what Congress intended in subsequently enacting a statute regulating a wholly different subject represents judicial overreaching that should deeply concern the Court and compel its review of the Court of Appeals' decision.

A. Factual Background

Nicorette is an over-the-counter (OTC) smoking cessation aid available in both 2 mg and 4 mg strength. When chewed, Nicorette provides a systemic release of nicotine, thereby reducing symptoms of nicotine withdrawal, including an individual's cravings for cigarettes. A new drug application (NDA) for Nicorette was first approved by FDA on January 13, 1984, permitting prescription-only use of the 2 mg strength gum as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. FDA approved

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1. It may be instructive for the Court to separately request from the Copyright Office, a legislative branch agency, its views on the issues raised in this petition.

Nicorette 4 mg strength for prescription-only use on June 8, 1992. Nicorette was approved by FDA for OTC sale on February 9, 1996. As a pioneer innovator drug, Nicorette was granted a three-year period of exclusivity in the OTC market pursuant to 21 U.S.C. § 355(c)(3)(D)(iii) (1999). That exclusivity period expired on February 9, 1999.

As part of the process of switching a prescription drug product to OTC status, the sponsor must obtain FDA approval of the labeling it proposes to use in connection with the OTC product. 21 U.S.C. § 355(a) (1999). Thus, SmithKline submitted various versions of the User's Guide and Audiotape to FDA between July 1993 and February 1996. In positioning Nicorette for the OTC market (in which Nicorette is sold with behavioral support materials for use without medical supervision), SmithKline strove to create a unified brand image consistent with its approach to quitting smoking. SmithKline's development of that approach evolved from its years of experience marketing Nicorette as a prescription drug and from extensive qualitative and quantitative market research conducted in an effort to understand the mindset of addicted cigarette smokers. Drawing upon this experience and research, SmithKline determined that it wanted to develop for Nicorette the brand image of an "encouraging friend," *i.e.*, that Nicorette offered the right amount of help and hope without overpromising its effectiveness or downplaying the difficulty of quitting smoking. The key selling line used for the launch of Nicorette in the OTC market – "You Can Do It – Nicorette Can Help" – reflects this positioning.

The district court found that SmithKline spent "several years and more than one million dollars developing a creative Guide and Tape that are an important part of the Nicorette

product and an important component of the brand image that SmithKline has sought to create." App. E at 50a. It further found that SmithKline's User's Guide and Audiotape "are copyrighted, creative materials." *Id.* at 45a. Far from containing a dry recitation of indications, dosage, side effects, and warnings, SmithKline's user-friendly illustrated User's Guide and dramatized Audiotape are the unique embodiments of SmithKline's carefully cultivated brand image for Nicorette. For example, in order to convey its "encouraging friend" brand image while informing consumers of the possibility of relapse, the Audiotape contains an enactment of a support group and of a relaxation session led by a fictional Dr. Yamato accompanied by soothing music. SmithKline's copyright resides in this creative expression, not in factual instructional text such as dosage information that also is contained in the User's Guide and Audiotape and on the Nicorette package.

Watson's Nicotine Polacrilex Gum, USP is an FDA-approved generic equivalent of Nicorette that is intended to be sold under private label by major retail chains nationwide in direct competition with Nicorette. On March 15, 1999, FDA approved Watson's ANDA for nicotine polacrilex gum. On July 28, 1999, SmithKline obtained from FDA a copy of the final approved labeling for Watson's Nicotine Polacrilex Gum, USP, 2 mg (nicotine), including a user's guide entitled "How To Use Nicotine Polacrilex Gum To Help You Quit Smoking." The court below found, and Watson has conceded, that Watson's guide and audiotape as originally approved by FDA copied virtually verbatim SmithKline's User's Guide in its entirety except for the substitution of Watson's name and telephone number for SmithKline's and the name of Watson's product for Nicorette. App. E at 46a.

B. District Court Proceedings

On August 27, 1999, SmithKline moved by order to show cause for a preliminary injunction to enjoin Watson from marketing a user's guide and/or audiotape that is strikingly or substantially similar to SmithKline's User's Guide and Audiotape. Watson argued in response that it was required to engage in verbatim copying by the FFDCA, as interpreted by FDA.[2] In response to the district court's request for clarification of FDA's position on copying of pioneer drug labeling by generic sponsors, Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research, wrote to the court and explained that, contrary to Watson's repeated representations to the court, the agency "does not approve the specific words or approach taken" by generic sponsors. Letter from Janet Woodcock, M.D. to The Honorable Denny Chin, dated September 9, 1999, attached as App. F. FDA also revealed that in a March 11, 1999 telephone conversation with Watson – prior to approval of the Watson labeling materials at issue – FDA had informed Watson that "the 'same labeling' requirement did *not* require that the generic's behavioral support materials be identical to the innovator's materials" (emphasis added). *Id.*[3]

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2. In attempting to present such purportedly mandated copying as a recognized copyright infringement defense, Watson initially offered three theories: (1) fair use; (2) the merger doctrine, *i.e.*, the User's Guide and Audiotape are not copyrightable; and (3) implied license. Watson subsequently dropped all but its fair use defense.

3. Watson subsequently admitted that FDA offered to consider noninfringing labeling but asserted that it determined that FDA's offer "lacked substance and . . . did not amount to an official policy change by FDA as a whole." A-472. ("A" refers to the joint appendix filed with the Second Circuit. "CA" refers to the confidential joint appendix.)
(Cont'd)

On September 10, 1999, the district court issued a Memorandum Decision granting SmithKline's motion for a preliminary injunction and ordering a recall of all product that Watson had disseminated accompanied by infringing behavioral support materials. App. E. In granting SmithKline's motion, the court observed that a *prima facie* case of copyright infringement gives rise to a presumption of irreparable harm and further found that even putting the presumption aside, SmithKline had demonstrated that it would suffer irreparable harm to its consumer goodwill should Watson's infringement not be enjoined. Although the district court did not fully address SmithKline's arguments on the merits, it did observe that "SmithKline argues forcefully that the FFDCA cannot have the effect of repealing the copyright laws and that the FFDCA cannot nullify its rights under the copyright laws." *Id.* at 51a. The court concluded that SmithKline had raised substantial issues that presented fair grounds for litigation and that the balance of the hardships tipped decidedly in SmithKline's favor. *Id.* at 52a.[4]

(Cont'd)
Watson also conceded that in early 1999, FDA asked Watson "whether Watson had concerns over copyright issues related to SmithKline's user's guide and audiotape" and that Watson assured FDA that the fair use doctrine would apply to Watson's copying. CA-11.

4. The district court's ruling as to the balance of the hardships was based in part on its finding that Watson's sole defense to the copyright infringement claim – that FDA required Watson's verbatim copying as a prerequisite to obtaining approval for its behavioral support materials – was discredited by FDA's September 9 letter to the court in which the agency stated that it did *not*, in fact, require generic behavioral support materials to be identical to those of the innovator drug. App. E at 54a. In addition, the district court found that any harm to Watson as a result of having shipped its product by overnight mail with knowledge of SmithKline's lawsuit was self-inflicted and not cognizable in balancing the hardships. *Id.* at 53a.

On September 17, 1999, the district court entered a preliminary injunction barring Watson from further sale and/or shipment of its generic smoking cessation product with a user's guide, audiotape, or other package insert "strikingly or substantially similar" to the Nicorette User's Guide and Audiotape and ordered Watson to recall any such nicotine gum that already had been shipped. App. D. On the same day, the district court denied Watson's application for a stay of the court's preliminary injunction order, finding both that Watson was not likely to succeed on appeal and that the equities tipped "decidedly in favor of SmithKline." App. C at 38a. The court held that "while the public does have a strong interest in having a generic version of [Nicorette] available, it also has a strong interest in the preservation of copyrights." *Id.* Finally, the court rejected Watson's argument that the public interest in having access to a generic version of Nicorette required a stay of the preliminary injunction, finding that "the unrestricted copying of copyrighted materials, developed only with great effort and at great expense, purportedly at the behest of the FDA when the FDA has acknowledged that it would consider non-identical materials, would not be in the public interest." *Id.* at 39a.

On October 5, 1999, with the consent of the parties, the district court granted a stay of proceedings for forty-five days to give Watson time to seek approval from FDA of revised labeling. At Watson's request, the court subsequently extended the stay until December 1, 1999.

On December 1, 1999, Watson filed a status report in which it advised the district court that on November 23, 1999, FDA had rejected revised materials submitted by Watson and was now requiring Watson "to copy verbatim large

portions of the [SmithKline] labeling." CA-2. Contrary to the position expressed in the Woodcock letter, the agency's latest letter to Watson showed that the agency was requiring Watson to copy a substantial amount of SmithKline's protected expression verbatim. CA-73-75. Nevertheless, the agency still was not requiring Watson to copy all of SmithKline's materials, but was allowing Watson to change certain copyrightable aspects of the materials, including text, graphics and music. *Id.*[5]

Based on FDA's change in position, Watson filed a motion with the district court on December 7, 1999 seeking modification of the preliminary injunction so as to allow it to market its gum with a user's guide and audiotape revised in accordance with FDA's instructions. At the district court's request, a representative from FDA was present at the December 8, 1999 hearing on Watson's motion. During the December 8, 1999 hearing, the court repeatedly admonished FDA to reconsider what the court called the "ridiculous" and "unreasonable" position taken by the agency in its November 23 letter, in which FDA allowed some changes but not others, without any apparent rhyme or reason. A-528. The court noted that it would "best serve the interests of the public to find some way to accommodate the goals of the copyright laws and the goals of the FDA laws." A-521.

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5. FDA's November 23 letter provided Watson with a "mock-up" of Watson's previously approved labeling – the same labeling that the district court found to be "copied, almost verbatim" from SmithKline's copyrighted materials. App. E at 50a. In the mock-up, FDA indicated in brackets the text for which Watson could substitute new text and instructed that all non-bracketed text remain identical to the earlier labeling.

The district court observed that as a "matter of common sense . . . there ha[ve] got to be different ways" of expressing certain phrases FDA was requiring Watson to copy verbatim from the Nicorette materials, and that "Watson could very easily rewrite that [language] slightly, convey the exact same concept, but the wording would be a little bit different and the copyright concerns would be substantially reduced." A-526-27. For example, the court noted that FDA was requiring Watson to copy the sentences "Quitting smoking is hard. If you['ve] tried to quit before and haven't succeeded, don't be discouraged." A-525. The court observed that "you can express these thoughts in many different ways" and noted its "great difficulty in understanding why the FDA says this must be identical." *Id.* The court expressed disbelief that FDA could be "wedded to those exact words" and asserted that if FDA "insists on this identical language, then [the court has] . . . to wrestle with this thorny question of the interplay between the two statutes." A-527-28.

On December 15, 1999, FDA submitted a letter to the district court in which it declined to reconsider its determination concerning Watson's revised behavioral support materials. Letter from Kim E. Dettelbach, Associate Chief Counsel, Food and Drug Administration, to The Honorable Denny Chin, dated December 15, 1999, attached as App. G. In that letter, FDA noted that it had not taken SmithKline's copyright rights into consideration in reviewing Watson's labeling because Congress had not given it any instructions for handling copyright issues. App. G at 64a. FDA also indicated that in addition to allowing Watson to deviate from SmithKline's labeling to the extent set forth in the November 23 letter, FDA would allow Watson to change

the headings contained in the User's Guide. *Id.* at 60a.[6] (Watson's materials revised in accordance with these instructions from FDA constitute the "New Behavioral Materials."). Thus, although FDA changed its position several times, and even after several months of litigation, FDA still was not interpreting "same as" as requiring identical, *i.e.*, word-for-word, copying.

On December 22, 1999, the district court granted Watson's motion and dissolved the preliminary injunction "to the extent that Watson is permitted to market and distribute its nicotine gum using the New Behavioral Materials." App. B at 36a. In its decision, the court summarily concluded that SmithKline had not demonstrated a likelihood of success on the merits despite finding that SmithKline's User's Guide and Audiotape are "not just 'labeling,' " but rather are "instructional materials that do involve a certain amount of creativity," App. B at 33a, and that the materials approved by FDA "indeed are identical in substantial respects to SmithKline's copyrighted materials." *Id.* at 30a. The court did not address Watson's unprecedented attempt to portray its conceded infringement as fair use, nor did it address SmithKline's argument that the court was required to attempt to harmonize the FFDCA and the Copyright Act – harmonization that the court itself had recognized at the December 8 hearing easily could be accomplished by requiring that the same information and

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6. Thus, for example, FDA agreed to permit Watson to use different words to convey the same meaning as the headings "Quitting Smoking is Hard" and "Let's Get Organized," yet it required verbatim copying of phrases such as "If you've tried to quit before and haven't succeeded, don't be discouraged!" and "Quitting isn't easy. It takes time. Most people try a few times before they are successful."

ideas be conveyed with different words. Instead, the court proceeded directly to balancing the hardships. In doing so, the court emphasized what it perceived to be the public's hardship should the injunction not be modified, finding that it would not be just to continue to enjoin Watson from marketing its product. The court concluded that the public's interest in having a cheaper generic smoking cessation alternative to Nicorette outweighed the public interest in protecting SmithKline's copyrights. App. B at 32a.[7]

C. Court of Appeals Proceedings

SmithKline timely appealed. In its brief to the Court of Appeals, Watson relied solely on fair use as a defense to its conceded copyright infringement. For its part, the United States Department of Justice (DOJ), in an *amicus* brief submitted on behalf of FDA at the court's request, took a different position than that presented to the district court by FDA. After stating that it had consulted with FDA, DOJ presented a position that represented at least the third change of course by the government on Watson's labeling. The government now asserted (for the first time) that SmithKline impliedly licensed its copyrighted material to generic competitors by submitting it to FDA for approval as labeling; however, it did not argue that the FFDCA abrogates the Copyright Act.

On April 4, 2000, the Second Circuit affirmed the district court's ruling and ordered the dismissal of SmithKline's complaint, finding that SmithKline's copyright infringement

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7. The court failed to acknowledge the availability of other OTC smoking cessation products already in the marketplace, including the Johnson & Johnson Nicotrol patch and the Perrigo Nicotine Transdermal System.

claims were foreclosed by the FFDCA. Although the Court of Appeals did "not doubt that SmithKline has demonstrated the existence of substantial issues under the copyright laws," App. A at 7a, the court concluded that "the Hatch-Waxman Amendments to the FFDCA not only permit but require producers of generic drugs to use the same labeling as was approved for, and is used in, the sale of the pioneer drug, even if that label has been copyrighted." *Id.* at 9a.[8]

Construing the statutory requirement that the proposed labeling for a generic drug be "the same as" that of the pioneer drug in light of Congress' goal of facilitating the approval and marketing of low-cost generic drugs, the court postulated that Congress must have envisioned that compliance with the "same as" requirement would lead to the creation of labeling that would be substantially similar to, and thus infringing of, pioneer labeling. App. A at 15a. The court speculated that Congress "would have provided explicitly that the Hatch-Waxman Amendments trump the copyright laws had it foreseen the statutory conflict exposed by the present action," *Id.* at 17a, and opined that the narrow permissible exceptions to identical copying contained in the statute were intended only to prevent factual misstatements rather than to avoid copyright infringement. *Id.* at 13a.

Addressing the apparent conflict between the FFDCA and the Copyright Act, the court purported to interpret both

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8. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), which amended the FFDCA to provide a more efficient procedure for approving generic drugs, is popularly known as the Hatch-Waxman Amendments.

statutes in a manner that "preserves the principal purposes of each." App. A at 14a. The court posited that recognition of SmithKline's copyright concerns would "severely undermine[]" the purposes of the Hatch-Waxman Amendments. *Id.* at 15a. On the other hand, the court reasoned that the purposes of the copyright laws would not be severely undermined by rejecting SmithKline's claim. *Id.* at 16a. In the court's view, the creativity of the authors of pioneer labeling is focused in part on obtaining FDA approval and the resulting statutory period of market exclusivity. *Id.* Because the FFDCA's period of market exclusivity provides an incentive to obtain approval of pioneer labeling, the court concluded that the purpose of the Copyright Act – to encourage the production of creative works by giving authors a property right in those works – "is not seriously implicated" by allowing the Hatch-Waxman Amendments to repeal the Copyright Act. *Id.* at 17a.

On June 8, 2000, after learning that, notwithstanding the Court of Appeals' decision, Watson was marketing its gum accompanied by FDA-approved labeling that differed in numerous respects from SmithKline's labeling, SmithKline moved for permission to file a petition for rehearing based on new evidence. SmithKline contended that FDA's approval of such non-identical labeling demonstrated that the FFDCA can be applied in a manner that accommodates copyright interests without undermining public health and safety or the integrity of FDA's regulatory scheme. SmithKline also moved for recall of the mandate. The Court of Appeals has not yet acted on these motions.

REASONS FOR GRANTING THE WRIT

I.

THIS CASE PRESENTS AN IMPORTANT QUESTION REGARDING THE PURPORTED CONFLICT BETWEEN TWO FEDERAL STATUTES

This case involves a Court of Appeals ruling that a federal statute regulating drug labeling impliedly repeals the constitutionally-grounded Copyright Act, even though the court conceded that Congress had not foreseen the purported statutory conflict in question. App. A at 17a (speculating that Congress "would have provided explicitly that the Hatch-Waxman Amendments trump the copyright laws had it foreseen the statutory conflict exposed by the present action"). The importance of the two statutes involved, and the consequences of the Court of Appeals' holding that judicial speculation as to congressional intent is a sufficient basis upon which to find partial repeal of the Copyright Act, should compel this Court to review this case. This Court previously has deemed conflicts between different bodies of federal law worthy of its attention. *See, e.g., Brown v. Pro Football, Inc.*, 518 U.S. 231 (1996) (labor laws and antitrust laws); *Vimar Seguros y Reaseguros, S.A. v. M/V Sky Reefer*, 515 U.S. 528 (1995) (Carriage of Goods by Sea Act and Federal Arbitration Act); *Watt v. Alaska*, 451 U.S. 259 (1981) (wildlife refuge laws and mineral leasing laws).

In confronting the issue of whether the FFDCA's "same as" requirement mandates wholesale copying by Watson of SmithKline's copyrighted behavioral support materials, the Court of Appeals held that copyright rights in creative materials such as illustrations and fictional support group

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DA review. In the Court of Appeals' view,
crafting the Hatch-Waxman Amendments with
acilitating competition from generic drugs, left
ccommodate the copyright interests of pioneer
ers. Contrary to the Court of Appeals' reasoning,
here is no basis to conclude that Congress
or intended this result, one which seriously
the goals and purposes of the copyright laws.

no genuine dispute that SmithKline holds valid
its User's Guide and Audiotape. Moreover, the
peals did not find that any of the statutory
o the exclusive rights of copyright holders, set
tions 107 through 119 of the Copyright Act,
107-119 (1999), apply to Watson's wholesale
e User's Guide and Audiotape. Indeed, the court
epticism regarding the only statutory defense
Watson relied on appeal, fair use.[9] Confronted,
seemingly direct conflict between the FFDCA
right Act, and in the absence of any recognized
Vatson's conceded copyright infringement, the
ed the conflict by interpreting the FFDCA as
pealing the Copyright Act, thus depriving
f the constitutionally-rooted right to protect its
property. *See* U.S. Const. art. 1, sec. 8, cl. 8
ngress the power "[t]o promote the Progress of

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ourt also expressed skepticism regarding the implied
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SmithKline's submission of its copyrighted materials
roval constituted implied consent for generic
copy those materials verbatim pursuant to the FFDCA.

Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"). The court's ruling rested on its speculation that had Congress, in passing the Hatch-Waxman Amendments, directly addressed the conflict between the two statutes (which the court acknowledged Congress had *not* done), it "*would have* provided explicitly that the Hatch-Waxman Amendments trump the copyright laws." App. A at 17a (emphasis added). The court thus effectively concocted a new exception to the rights enumerated in section 106 of the Copyright Act despite the acknowledged absence of any indication that Congress intended to create such an exception.

This cavalier abridgment of SmithKline's copyright rights, based upon the court's hypothesized version of congressional intent rather than express congressional authorization, sets a troubling precedent. The proposition that a company necessarily donates its copyrighted material to future competitors when it submits that material to a federal agency for approval represents a nullification of intellectual property rights that should not be effectuated solely on the basis of judicial speculation as to Congress' intent.

The Hatch-Waxman Amendments and the Copyright Act, respectively, regulate different interests and have different purposes; defining the scope of copyright protection in labeling materials submitted in support of an NDA is not among the subjects regulated by the FFDCA. As this Court recently cautioned:

> [A]n administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. . . . [I]n

> our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.

Food and Drug Administration v. Brown & Williamson Tobacco Corp., 120 S. Ct. 1291, 1315 (2000) (citations omitted). Here, the Court of Appeals required FDA to override the copyrights in the User's Guide and Audiotape without any express congressional grant of such power to the agency.

In a consumer culture in which the creation of ever more effective, attractive, user-friendly products is stimulated in no small part by the protection of intellectual property rights, the Court of Appeals' ruling erodes intellectual property protection for innovative drug labeling in a manner that will undermine the incentive to invest creative resources in such labeling, to the detriment of the consuming public. If copyrightable labeling materials are to be donated to competitors by dint of judicial partiality toward administrative goals at the expense of intellectual property rights, companies will be inhibited from seeking to improve the way product information is communicated to the consuming public, resulting in a loss of creativity in the commercial sphere and permanent damage to the Copyright Act.

II.

THE COURT OF APPEALS' DECISION CONFLICTS WITH DECISIONS OF THIS COURT REQUIRING THAT COURTS ATTEMPT TO HARMONIZE CONFLICTING FEDERAL STATUTES BEFORE FINDING IMPLIED REPEAL

The Court of Appeals' decision violates two complementary canons of statutory construction: first, that repeals by implication are disfavored, *see United States v. Borden Co.*, 308 U.S. 188, 198 (1939) (it is a "cardinal principle . . . that repeals by implication are not favored."); *Watt v. Alaska*, 451 U.S. 259, 267 (1981); and second, that in the event of a conflict between two federal statutes, a court must, prior to finding an implied repeal of the former by the latter, attempt to harmonize the laws by adopting "the interpretation that preserves the principal purposes of each." App. A at 14a (*citing Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999)). *See also Morton v. Mancari*, 417 U.S. 535, 551 (1974) (where two federal statutes seem to conflict, it is the "duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective"); *Borden*, 308 U.S. at 198 ("When there are two acts upon the same subject, the rule is to give effect to both if possible."). While purporting to harmonize the FFDCA and the Copyright Act, the Court of Appeals instead erroneously held that the FFDCA overrides the Copyright Act with respect to generic drug labeling, notwithstanding the fact that harmonization easily could have been accomplished.

The Court of Appeals acknowledged that Congress did not, either in the FFDCA itself or in the legislative history,

manifest an intention to override the Copyright Act and, in fact, did not even anticipate the statutory conflict presented in this case. App. A at 17a. That acknowledgment should have led the court to attempt to harmonize the two statutes. Instead, the court asserted that had it foreseen the conflict, Congress "*would have* provided explicitly that the Hatch-Waxman Amendments trump the copyright laws." *Id.* at 17a (emphasis added). In support of its interpretation of Congress' intent with respect to the "same as" requirement, the court stated:

> [W]here the language of a document is the "same" as that of a copyrighted work, the former usually infringes the latter. Certainly, a legislative drafter would believe that a sameness requirement would lead to the creation of works that would easily fall within the copyright law's infringement test of "substantial similarity."

Id. at 12a. However, while it may be reasonable to presume that Congress envisioned identical copying of the factual information contained in the pioneer drug labeling, the fact is that most drug labeling does not contain significant, if any, copyrightable expression, as do the behavioral support materials at issue here. Thus, the pertinent question in this case is whether Congress considered and addressed the situation in which the copying purportedly mandated by the "same as" requirement would result in copyright infringement. The answer to that question, as the Court of Appeals conceded, is no. Accordingly, the court's conclusion that Congress intended to partially repeal the Copyright Act is without basis.

The Court of Appeals' unwarranted presumption that Congress intended the "same as" requirement to partially repeal the Copyright Act led the court to "reconcile" the conflicting statutes in a manner that turned on its head the principle that repeals by implication are disfavored. Whereas FDA, at several points during the district court proceedings, as well as the district court itself, expressed recognition that some accommodation of SmithKline's copyright concerns was possible within the parameters of the FFDCA, the Court of Appeals refused to consider any such reconciliation of the two statutes.

Paying lip service to its obligation to harmonize the conflicting statutes in a manner that preserves the purposes of each, the Court of Appeals concluded that accommodating SmithKline's copyright interests would "severely undermine[]" the purposes of the Hatch-Waxman Amendments by creating a situation in which "producers of generic drugs will always be delayed in – and quite often prohibited from – marketing the generic product. . . ." App. A at 15a-16a. But this conclusion is undermined by the fact that harmonization clearly is possible without imposing an undue administrative burden on FDA, in part because this issue will not arise in connection with all generic drugs.

There is no record support for the Court of Appeals' assertion that identification by FDA of those aspects of the pioneer labeling that are copyrightable and need not be copied exactly would "drain the resources of the FDA and generic producer." App. A at 15a. To the contrary, FDA's December 15 letter to the district court, while imperfect in its failure to fully accommodate SmithKline's copyright interests, distinguished between specific categories of

information that, pursuant to FDA regulations, were labeling subject to FDA approval and thus had to be copied exactly and other aspects of SmithKline's labeling that did not have to be copied verbatim. App. G at 62a. FDA represented that only text required to be reviewed by the agency under 21 C.F.R. § 201.66 (encompassing product description, principal intended pharmacological action, indications and usage, dosage and administration, warnings, side effects, and directions for use, *see* App. H) had to be copied exactly. *Id.* at 62a-63a. With respect to "additional information" or "content outside of the scope of 21 C.F.R. § 201.66," including "specific relaxation tips, examples of strategies to fight temptation, music, graphics, actors or characters," FDA determined that Watson had the discretion to use "different words to convey the important concepts that FDA identified in a truthful, non-misleading presentation and a comparable format." *Id.* at 63a. Such a determination, in FDA's view, "focused on the requirements of Waxman-Hatch [sic] for generic drug approvals and the FDA's mission to protect public health, while providing the generic some flexibility in addressing the copyright protections that SmithKline claims for its labeling." *Id.*[10]

Thus, prior to changing its position on appeal, FDA saw that it was possible to fulfill the purpose of the FFDCA without riding roughshod over the pioneer manufacturer's copyright interests – in other words, that the FFDCA and

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10. Even if some administrative burden is imposed by the task of taking copyright interests into account in reviewing generic labeling, there is no basis for concluding, as the Court of Appeals did, that such a situation will arise in connection with most, or even many, generic drugs, or that the burden in such cases justifies the substantial incursion on the pioneer manufacturer's copyright rights that occurred here.

the Copyright Act can be harmonized without undermining the generic drug regulatory scheme. Such an interpretation of the FFDCA eschews an unreasonably literal reading of the "same as" requirement without significantly impairing the generic drug approval process, while at the same time preserving the integrity of the copyright laws. Such an interpretation also is consistent with FDA's view that "most labeling changes that do not involve serious health or safety effects will be acceptable without new pharmacokinetic data." *Rules and Regulations: Abbreviated New Drug Application Regulations*, 57 Fed. Reg. 17,950, 17,962 (FDA 1992). That view stems from the agency's recognition that the overarching purpose of the generic labeling requirement "is to assure the marketing of generic drugs that are as safe and effective as their brand-name counterparts." *Proposed Rules: Abbreviated New Drug Applications Regulations*, 54 Fed. Reg. 28,872, 28,884 (FDA 1989). Permitting deviations from creative aspects of pioneer labeling will in no way undermine that purpose.

On the other side of the scale, although the Court of Appeals correctly identified the purpose of the copyright laws as "encourag[ing] the production of creative works by according authors a property right in their works so that authors will not have to share profits from their labors with free riders," App. A at 17a, it wrongly concluded that this purpose "is not seriously implicated" by allowing the FFDCA's "same" labeling requirement to trump SmithKline's copyright rights. *Id.*

The court's error lay in mistakenly characterizing the copyright interest as residing in the incentive to create labeling needed for FDA approval. App. A at 17a-18a ("It is simply not conceivable that, if we reject SmithKline's

claim, pioneer drug producers will so fear the copying of labels by future generic drug producers that some pioneer producers – or even one of them – will lack the incentive to create labeling needed for FDA approval."). In fact, the Copyright Act provides the incentive to create *creative, copyrightable labeling materials*, such as those at issue in this case, in order to enhance the product's brand image and improve its saleability of the product. The limited market exclusivity provided by the Hatch-Waxman Amendments *is* an incentive to obtain FDA approval for pioneer drug labeling, but it is *not* an incentive to create the copyrightable aspects of the labeling. Absent this latter incentive, which is provided by the Copyright Act but not by the FFDCA, the purpose of the Copyright Act will be undermined by allowing free-riders to profit from the pioneer's copyrightable expression. *See Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975) ("[T]he ultimate aim is, by this incentive, to stimulate artistic creativity for the general public good.").

Further, the Court of Appeals' conclusion that the "same as" requirement mandates identical copying except where deviations are required to avoid factual misstatement leads to absurd results. For instance, it will, if taken literally, require Watson to copy SmithKline's Audiotape in every particular – including support group and relaxation session enactments, the fictional Dr. Yamato character, and other primarily creative aspects of the SmithKline materials. Had SmithKline hired Harrison Ford to record the Audiotape, the Court of Appeals' decision would seem to require every generic manufacturer to use Harrison Ford on their audiotapes as well, thus violating not only copyright rights but publicity rights as well.

The choice thus confronted by manufacturers of those pioneer drugs for which behavioral support materials are necessary is to eliminate all "creative" aspects of the labeling, thus making the materials as dry and clinical as possible, or to donate their creative efforts to generic competitors. The unattractiveness of the second option is such that the incentive to creativity otherwise provided by the copyright laws will be lost, thus belying the Court of Appeals' assertion that allowing the FFDCA to trump the Copyright Act will not undermine the latter.[11]

Had the Court of Appeals undertaken seriously to harmonize the FFDCA and the Copyright Act, rather than allowing the former to trump the latter, it would have

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11. The Court of Appeals' ruling also is inconsistent with rulings by the Second Circuit and at least one other circuit that government reference to copyrighted material in a regulatory scheme does not deprive that material of copyright protection. *See CCC Info. Serv., Inc. v. Maclean Hunter Mkt. Reports, Inc.*, 44 F.3d 61, 74 (2d Cir. 1994) (rejecting argument that reference to copyrighted used car valuations in state insurance statutes or regulations injects the valuations into the public domain, resulting in loss of copyright); *Practice Management Info. Corp. v. American Med. Ass'n*, 121 F.3d 516, 519 (9th Cir. 1997) (rejecting argument that adoption of copyrighted medical procedure code by the Health Care Financing Administration invalidated the copyright in the code). The principle involved in this case and in *CCC Info Serv.* and *Practice Management* is the same: just as the adoption by a government entity of a copyrighted work as an official standard does not deprive the author of the copyrighted work of copyright protection, FDA's approval of SmithKline's User's Guide and Audiotape in connection with SmithKline's NDA (thus making those the standard behavioral support materials for nicotine polacrilex gum) cannot deprive SmithKline of its intellectual property rights in the copyrightable aspects of those materials.

interpreted the "same as" requirement as mandating that the new drug's labeling convey to consumers all facts and information relating to the safe and effective use of the product at issue without copying the precise manner in which this information is expressed by the pioneer drug's copyrighted labeling.

CONCLUSION

For all the reasons set forth above, a writ of certiorari should issue to review the judgment of the Court of Appeals for the Second Circuit.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DATED AND DECIDED APRIL 4, 2000

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 1999

(Argued: January 13, 2000 Decided: April 4, 2000)

Docket No. 99-9501

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Plaintiff-Appellant,

– v. –

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and CIRCA PHARMACEUTICALS, INC.,

Defendants-Appellees.

Before: WINTER, *Chief Judge*, JACOBS, and KATZMANN, *Circuit Judges*.

Appeal from an order of the United States District Court for the Southern District of New York (Denny Chin, *Judge*) dissolving a preliminary injunction that prevented Watson Pharmaceuticals from infringing upon SmithKline's copyrighted label used on its Nicorette gum in Watson's

marketing of a competitive nicotine gum. Because the FDA required Watson to use the infringing label in selling its drug, the injunction effectively prevented Watson from making sales. We hold that the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require generic drug sellers to use labeling that may infringe a copyright in the label of the pioneer drug. We further hold that, as a result, copyright liability cannot attach to Watson's use of SmithKline's label. We therefore affirm.

* * *

WINTER, *Chief Judge*:

This appeal arises out of a copyright action alleging infringement of appellant's copyright in a user's guide and audiotape developed for its Nicorette-brand gum. Appellees, in obtaining approval to sell a competing generic nicotine gum product, were directed by the Food and Drug Administration ("FDA") to use labeling almost identical to appellant's copyrighted guide and tape. The FDA acted pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *see* Drug Price Competition and Patent Term Restoration Act of 1984 § 101, 21 U.S.C. § 355(j) ("Hatch-Waxman Amendments"). Judge Chin initially enjoined appellees from selling or shipping its nicotine gum with the infringing label. *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 63 F. Supp. 2d 467, 473 (S.D.N.Y. 1999) ("SmithKline I"). Subsequently, the district court determined that the balance of the hardships tilted in favor of appellees and dissolved its earlier injunction, *see SmithKline Beecham*

Appendix A

Consumer Healthcare, L.P. v. Watson Pharms., Inc., No. 99 Civ. 9214, 1999 WL 1243894, at *5-*7 (S.D.N.Y. Dec. 22, 1999) ("SmithKline II"), and SmithKline appealed.

Appellees cannot be liable for copyright infringement because the Hatch-Waxman Amendments require generic drug producers to use the same labeling as was approved by the FDA for, and is used by, the producer of the pioneer drug. We therefore affirm.

BACKGROUND

Appellant SmithKline Beecham Consumer Healthcare, L.P. ("SmithKline") manufactures and sells Nicorette nicotine polacrilex gum ("Nicorette"), an over-the-counter ("OTC") product designed to help smokers overcome the cigarette habit. The FDA administrative history of Nicorette, which was the subject of a patent, is as follows. On January 13, 1984, SmithKline obtained FDA approval to sell 2 mg strength Nicorette for prescription-only use. Later, on June 8, 1992, the FDA approved prescription-only use of 4 mg Nicorette. Finally, on February 9, 1996, the FDA approved both 2 mg and 4 mg Nicorette for OTC sale. Pursuant to 21 U.S.C. § 355(c)(3)(D)(iv), SmithKline obtained a three-year period of exclusivity — essentially an extension of the effective term of SmithKline's Nicorette patent based on additional clinical testing — for OTC sale of Nicorette.

SmithKline's user's guide and audiotape were developed in the course of its research into producing a method of, and product for, quitting smoking. To obtain approval for the

OTC sale of Nicorette, SmithKline submitted various versions of the guide and tape to the FDA for review. *See* 21 U.S.C. § 355(b)(1)(F) (requiring application for approval of drug to include "specimens of the labeling proposed to be used for such drug"). Between July 1993 and February 1996, SmithKline made approximately 70 changes to the guide and the tape at the FDA's request. Most of the changes related to factual matters, safety, and efficiency. The tape and guide were ultimately included as part of Nicorette's FDA-approved OTC labeling. On April 21, 1998, SmithKline registered a federal copyright for the guide and audiotape script. On February 9, 1999, the day when its exclusivity period for Nicorette expired, SmithKline registered a copyright for the words and music on the tape.

Shortly thereafter, appellees Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. (collectively "Watson") obtained FDA approval for the OTC marketing of a generic version of nicotine gum intended to compete directly with Nicorette. To obtain that approval from the FDA, Watson had to comply with the requirement imposed by the Hatch-Waxman Amendments that "the labeling proposed for [its] new drug [be] the same as the labeling approved for" Nicorette. 21 U.S.C. § 355(j)(2)(A)(v); *see also* 21 C.F.R. § 314.127(a)(7) ("FDA will refuse to approve an abbreviated application for a new drug under section 505(j) of the act [if] . . . . [i]nformation submitted in the abbreviated new drug application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug. . . ."). Thus, Watson's generic nicotine gum was "accompanied by a user guide and audio tape that [we]re virtually identical to SmithKline's." *SmithKline I*, 63 F. Supp. 2d at 469.

Appendix A

Before Watson could sell its product to the public, SmithKline initiated the present copyright action, alleging willful infringement of its guide and tape. The district court granted a preliminary injunction that effectively stopped Watson from shipping or selling its product. *See id.* at 473. The district court relied on a March 1999 FDA letter recounting that the agency had explained to Watson that "the 'same labeling' requirement d[oes] not require that the generic's behavioral support materials be identical to the innovator's materials" and indeed that "generic sponsors, like all other sponsors of nicotine-based smoking cessation aids, have discretion to design their own audio support materials." *Id.* at 470. Based on this representation, the district court "concluded that the FDA would have permitted Watson to use a user's guide and audio tape that deviated to some extent from SmithKline's materials . . . [and] that were sufficiently different in wording and otherwise to avoid copyright concerns." *SmithKline II*, 1999 WL 1243894, at *3.

Subsequently, the FDA altered its position. In the face of the preliminary injunction, Watson revised its guide and tape to render them "comparable, but not identical, to SmithKline's." *Id.* However, on November 23, 1999, the FDA rejected the revised user guide. The FDA "advised Watson that it would approve a revised version of Watson's 'previously approved labeling,' *i.e.*, the virtually identical user's guide previously approved by the FDA." *Id.* To assist Watson, the FDA "marked up a copy of the previously approved user guide" and bracketed certain portions of text which could be in appropriate cases deleted or "substituted with new text . . . . similar to the original in tone, content

and length." *Id.* Nevertheless, the bracketed guide gave Watson "very little leeway to deviate from the previously approved user guide." *Id.* In essence, therefore, the FDA "determined that Watson had to copy verbatim substantially all of the text used in the SmithKline" user's guide. *Id.* at *4.

In December, representatives of the FDA attended a conference with the district court, at which time the court asked the FDA to " 'revisit' the question of whether portions of Watson's proposed user's guide could be rewritten to change the text 'a little bit' to address the copyright concerns." *Id.* On December 15, the FDA wrote the court and advised that it had "decline[d] to change its approach to Watson's labeling" and that it could not address copyright concerns because it "ha[d] never been directed by Congress to consider potential copyright rights in approving generic drug labeling." *Id.* In a supplemental decision issued the same day, the FDA "adhered to its decision to require Watson to copy verbatim most of the SmithKline" user guide. *Id.*

In light of the FDA's position, the district court dissolved the preliminary injunction, citing also Watson's efforts to revise its materials, the prejudice caused Watson by delay, and the public interest in a generic nicotine gum product. *See id.* at *5-*7. We granted SmithKline's motion for a stay and expedited the appeal.

DISCUSSION

A preliminary injunction may issue only if the plaintiff demonstrates irreparable harm, and either a likelihood of

success on the merits, or sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in its favor. *See Otokoyama Co. v. Wine of Japan Import, Inc.*, 175 F.3d 266, 270 (2d Cir. 1999). We may overturn a district court's decision to dissolve a preliminary injunction only if it constitutes an abuse of discretion, "which usually involves either the application of an incorrect legal standard or reliance on clearly erroneous findings of fact." *ABKCO Music, Inc. v. Stellar Records, Inc.*, 96 F.3d 60, 64 (2d Cir. 1996); *accord Niagara Hooker Employees Union v. Occidental Chem. Corp.*, 935 F.2d 1370, 1374 (2d Cir. 1991).

In ruling on an interlocutory appeal, we generally "will go no further into the merits than is necessary to decide the interlocutory appeal." *American Cyanamid Corp. v. Connaught Lab., Inc.*, 800 F.2d 306, 310 (2d Cir. 1986) (quoting *Hurwitz v. Dirs. Guild of Am., Inc.*, 364 F.2d 67, 70 (2d Cir. 1966)). However, "this rule is subject to a general exception — [we] may dismiss the complaint on the merits if [our] examination of the record . . . reveals that the case is entirely void of merit." *Id.* (dismissing trademark infringement action on appeal of preliminary injunction (quoting *Hurwitz*, 364 F.2d at 70)). This appeal falls within that exception.

We do not doubt that SmithKline has demonstrated the existence of substantial issues under the copyright laws, at least when they are considered in isolation. *See* 17 U.S.C. §§ 101 *et seq.* SmithKline's guide and tape are creative works in which it has a substantial investment, and they are integral to both the marketing and use of Nicorette. Watson's guide

and tape are concededly in large part copies of SmithKline's copyrighted materials. Moreover, Watson intends to use the guide and tape in marketing a product in direct competition with SmithKline's gum. Absent more, the propriety of a preliminary injunction would seem clear.

Watson asserts that this copying, having been dictated by the FDA, is a "fair use" protected under 17 U.S.C. § 107. The United States, in its *amicus curiae* brief, argues instead that in submitting its copyrighted materials for FDA approval, SmithKline gave the FDA an implied, nonexclusive license to permit or require generic drug applicants to copy the user's guide and audiotape in their own nicotine gum packaging.

Neither fair use nor implied license is clearly a defense in the present circumstances. Watson's use of SmithKline's copyrighted works in its labeling is rather different from the sorts of copying traditionally deemed to constitute a fair use, *e.g.*, copying for "purposes such as criticism, comment, news reporting, teaching . . ., scholarship, or research." *See* 17 U.S.C. § 107. Moreover, courts have found implied licenses only in "narrow" circumstances where one party "created a work at [the other's] request and handed it over, intending that [the other] copy and distribute it." *Effects Assocs. Inc. v. Cohen*, 908 F.2d 555, 558 (9th Cir. 1990); *see also Korman v. HBC Fla., Inc.*, 182 F.3d 1291, 1293 (11th Cir. 1999) (determining that plaintiff gave defendant radio station implied, nonexclusive license to use jingles she had written for station).

However, we see little need for further examination of these possible defenses.[1] If either were to prevail, some new law, essentially judge-made, would have to be fashioned. In our view, the case can more easily be disposed of on the straightforward ground that the Hatch-Waxman Amendments to the FFDCA not only permit but require producers of generic drugs to use the same labeling as was approved for, and is used in, the sale of the pioneer drug, even if that label has been copyrighted. Because those Amendments were designed to facilitate rather than impede the approval and OTC sale of generic drugs, the FDA's requirement that Watson use much of SmithKline's label precludes a copyright infringement action by SmithKline. SmithKline's copyright claim is therefore meritless, and we need not address either the fair use or implied license defenses.

The FFDCA prohibits the sale of drugs that are not first approved by the FDA. *See* 21 U.S.C. § 355(a); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-13 (1973). To gain FDA approval, manufacturers of new drugs must generally submit a "new drug application" ("NDA") that demonstrates the drug's safety and efficacy for its intended uses. *See* 21 U.S.C. § 355(b). The NDA must include, *inter alia*, drug samples, proposed labeling, and the results of clinical safety and efficacy tests. *See id.*; *see also* 21 C.F.R. § 314.50.

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1. The implied license issue is somewhat superfluous in that the license would have to be inferred from the Hatch-Waxman requirement that copyright labels be infringed. If that view of Hatch-Waxman is correct, as the present opinion holds, then the outcome is dispositively determined without further discussion of the doctrine of implied license.

Appendix A

Generic drugs are identical to pioneer drugs that have previously obtained FDA approval; they can be marketed once the pioneer drug's patent protection and FFDCA exclusivity periods expire. *See* H. Rep. No. 98-857, Part I, at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649; *see also* 21 U.S.C. § 355(j)(2)(A)(vii). In 1984, the Hatch-Waxman Amendments were enacted "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs. . . ." 1984 U.S.C.C.A.N. at 2647. The Amendments provided that, rather than filing a complete NDA, manufacturers of generic drugs need complete only an "abbreviated new drug application" ("ANDA"), which could essentially piggy-back on the pioneer drug's human clinical trials and labeling. *See* 1984 U.S.C.C.A.N. at 2649.

The Hatch-Waxman Amendments reflect the FDA's view that clinical retesting of generic drugs was "unnecessary and wasteful because the drug ha[d] already been determined to be safe and effective," as well as "unethical because it [would] require [ ] that some sick patients take placebos and be denied treatment known to be effective." *Id.* Bypassing redundant human testing would also speed up FDA approval for generic entrants and thus introduce price competition more rapidly once the pioneer producer's patent and exclusivity periods expired. *See Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988) (interpreting congressional purpose of Hatch-Waxman Amendments to be "increas[ing] competition in the drug industry by facilitating the approval of generic copies of drugs").

Except for human clinical tests, the ANDA requires a manufacturer to submit to the FDA the same items as required in the NDA, *see* 21 U.S.C. § 355(j)(2)(A)(vi); 1984 U.S.C.C.A.N. at 2649 ("The only difference between a NDA and an ANDA is that the generic manufacturer is not required to conduct human clinical trials."), as well as information to show that the generic drug has the same active ingredients, means of administration, dosage form, strength, pharmacological or therapeutic class, and labeling as the already-approved pioneer drug, and that the generic drug does not infringe any outstanding patents. *See generally* 21 U.S.C. § 355(j)(2)(A).

With specific regard to labeling, the Hatch-Waxman Amendments require that an ANDA "show that the labeling proposed for the [generic] drug is the same as the labeling proposed for the [pioneer] drug . . . except for changes required because of [approved] differences [between the pioneer and generic drug] or because the [generic] drug and [pioneer] drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v). The FFDCA defines "label" and "labeling" for these purposes as "a display of written, printed, or graphic matter upon the immediate container of any article" or "accompanying such article," 21 U.S.C. § 321(k) & (m), which the FDA has broadly interpreted to include "[b]rochures, booklets . . . sound recordings, . . . and similar pieces of printed, audio, or visual matter descriptive of a drug." 21 C.F.R. § 202.1(1)(2).

Applying the Hatch-Waxman Amendments to the present appeal, SmithKline's copyright claim fails. First, its

copyrighted user's guide and audiotape constitute "labeling" for purposes of the Hatch-Waxman Amendments. SmithKline has not contended otherwise and understandably so. The guide and tape clearly fall within the statutory and regulatory definitions quoted immediately above. Moreover, they were submitted to the FDA as part of SmithKline's quest for administrative approval of OTC sales of Nicorette. The guide and tape were approved only after more than two years of administrative consideration and after that consideration had led to some 70 changes in the guide and tape at the FDA's request.

Second, the FDA's requirement that Watson use copious amounts of SmithKline's copyrighted material is not a misapplication of the Hatch-Waxman Amendments. As noted, the Amendments require that the labeling for the generic drug be the "same" as the labeling for the pioneer drug. *See* 21 U.S.C. § 355(j)(2)(A)(v). To be sure, as SmithKline noted at oral argument, "same" may be something less than "identical." However, where the language of a document is the "same" as that of a copyrighted work, the former usually infringes the latter. Certainly, a legislative drafter would believe that a sameness requirement would lead to the creation of works that would easily fall within the copyright law's infringement test of "substantial similarity." *See, e.g., Hamil Am., Inc. v. GFI*, 193 F.3d 92, 99 (2d Cir. 1999) ("To prove infringement, a plaintiff with a valid copyright must demonstrate that: (1) the defendant has actually copied the plaintiff's work; and (2) the copying is illegal because a substantial similarity exists between the defendant's work and the protectible elements of plaintiff's." (internal quotation marks omitted)),

cert. denied, 120 S. Ct. 1171 (2000).[2] Indeed, the legislative history of the Hatch-Waxman Amendments suggests that whatever difference may exist between "same" and "identical" is narrow and intended to prevent misstatements rather than infringement:

> [A]n ANDA must contain adequate information to show that the proposed labeling for the generic drug is the same as that of the listed drug. The Committee recognizes that the proposed labeling for the generic drug may not be exactly the same. For example, the name and address of the manufacturers would vary as might the expiration dates for the two products. Another example is that one color is used in the coating of the listed drug and another color is used in that of

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2. Some courts have held that infringement of a copyright in commercial labeling must involve verbatim or near-verbatim copying. *See, e.g., Sassafras Enters., Inc. v. Roshco, Inc.*, 889 F. Supp. 343, 345 (N.D. Ill. 1995) (in copyright labeling claim, "[a]bsent verbatim or near-verbatim copying, no infringement exists"). However, this heightened standard typically involves a copyrighted label of a "fact-based work[ ]," *id.* at 347, and SmithKline's guide and tape are substantially more creative than the typical commercial labels afforded copyright protection. We need not decide whether the traditional "substantial similarity" infringement test or a heightened "verbatim or near-verbatim" test applies to the instant case. As discussed *infra*, the plain language of the Hatch-Waxman Amendments, their legislative history, and their interpretation by the FDA all require manufacturers of generic drugs to copy the labeling of pioneer drugs "near-verbatim" to obtain ANDA approval, and this statutory mandate necessarily trumps any copyright interest in the label at issue.

> the generic drug. The FDA might require the listed drug maker to specify the color in its label. The generic manufacturer, which has used a different color, would have to specify a different color in its label.

H. Rep. No. 98-857, Part I, at 22 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2655.

Third, if SmithKline's copyright claim has merit, then Watson cannot realistically use the ANDA process to sell its generic nicotine gum because it will either have to change the label and lose FDA approval or be enjoined from using a label that infringes SmithKline's copyright. We are thus faced with a conflict between two statutes. The Hatch-Waxman Amendments require generic drug producers to use labeling that will infringe upon copyrights in labels of pioneer drugs. The Copyright Act seems to prohibit such copying. However, applying the familiar canon that, where two laws are in conflict, courts should adopt the interpretation that preserves the principal purposes of each, *see, e.g.*, *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999) ("Unless Congress clearly indicates which of two statutes is to prevail in event of conflict, our responsibility is to interpret and apply them 'in a way that preserves the purposes of both and fosters harmony between them.' " (quoting *Vornado Air Circulation Sys., Inc. v. Duracraft Corp.*, 58 F.3d 1498, 1507 (10th Cir. 1995))),[3] the conflict is less stark and more easily resolved than it might seem.

3. In addition to looking to conflicting statutes' principal purposes, courts have traditionally given weight to statutes' priority of enactment and specificity in reconciling conflicts. *See, e.g.*, *FDA* (Cont'd)

Appendix A

The purposes of the Hatch-Waxman Amendments would be severely undermined if copyright concerns were to shape the FDA's application of the "same" labeling requirement. The Amendments were intended to facilitate the introduction of generic competitors once a pioneer drug's patent term and exclusivity periods had ended by allowing the generic producer to piggy-back upon the pioneer producer's successful FDA application. For example, human testing by the generic producer is not required because it would be time-and-resource-consuming even though redundant. For the very same reason, the creation and approval of new labels is avoided by the "same" labeling requirement. If labels that were "substantially similar" to copyrighted labels on pioneer drugs had to be avoided, the administrative process of approving a new label would, in cases like the present one, drain the resources of the FDA and generic producer — not to mention the problem of successive generic producers

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(Cont'd)

v. Brown & Williamson Tobacco Corp., No. 98-1152, 2000 WL 289576, at *13 (Mar. 21, 2000) ("The classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. . . . [A] specific policy embodied in a later federal statute should control our construction of the earlier statute, even though it has not been expressly amended." (internal quotation marks, brackets, and citations omitted)). Here, of course, both time of enactment and specificity favor our interpretation: the Hatch-Waxman Amendments were enacted subsequent to the Copyright Act of 1976, and the Copyright Act's broad generality contrasts with the Hatch-Waxman Amendments' specific generic drug approval scheme.

avoiding infringement of multiple copyrighted labels. Avoiding such infringement would also delay the introduction of the generic product without advancing public health and safety to any perceptible degree. For that reason, Congress left no room for such redundant proceedings and adopted the "same" labeling requirement. The FDA cannot be faithful to that requirement, however, without requiring labels that will often violate copyrights. If copyright law were to prevail, producers of generic drugs will always be delayed in — and quite often prohibited from — marketing the generic product, results at great odds with the purposes of the Hatch-Waxman Amendments.

No such severe undermining of the purpose of the copyright laws would follow from the rejection of SmithKline's claim, however. The creation of labels to be approved by the FDA, such as SmithKline's user's guide and audio tape, is ancillary to the FDA's administrative process. The creativity of the author is focused not only on pleasing and medicating ultimate consumers but also on obtaining the administrative approval of labeling necessary to FDA approval of a drug that will be protected from competition both for the period of the patent term and FFDCA exclusivity periods.[4]

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4. Indeed, Congress enacted the Hatch-Waxman Amendments as a partial amendment to the patent laws. It extended patent length for drugs to accommodate the delay caused by the FDA's testing process and slightly weakened patentholders' rights by permitting prospective manufacturers of generic drugs to engage in preliminary testing pursuant to ANDAs before pioneer drugs' patents or terms of exclusivity had fully expired. *See* 1984 U.S.C.C.A.N. at 2714 & n.20.

Our point here is not only that Congress would have provided explicitly that the Hatch-Waxman Amendments trump the copyright laws had it foreseen the statutory conflict exposed by the present action, although we firmly believe that to be obvious. Our point is also that the profit sought by the creator of the pioneer drug label flows primarily from the administrative approval of the drug and the patent and exclusivity periods free from competition that follow. The pertinent purpose of the copyright laws — to encourage the production of creative works by according authors a property right in their works so that authors will not have to share profits from their labors with free riders, *see, e.g.*, *Mazer v. Stein*, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the [copyright] clause . . . is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare. . . ."); *see also Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975) ("[T]he ultimate aim is, by this incentive, to stimulate artistic creativity for the general public good."); *cf. Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 586 (1994) (emphasizing that "some works are closer to the core of intended copyright protection than others" in assessing fair use defense to claim that parody infringed on valid copyright) — is not seriously implicated by allowing the "same" labeling requirement to trump a copyright under the Hatch-Waxman Amendments.[5] It is simply not conceivable that, if

5. Although commercial labeling is clearly copyrightable, *see* 1 *Nimmer on Copyright* § 2.08[G], at 2-135 ("It is clear that [17 U.S.C. §] 102(a)(5) includes prints and labels used for articles of merchandise under the general protection accorded to pictorial, graphic and sculptural works." (citing H.R. Rep. No. 94-1476,

(Cont'd)

we reject SmithKline's claim, pioneer drug producers will so fear the copying of labels by future generic drug producers that some pioneer producers — or even one of them — will lack the incentive to create labeling needed for FDA approval.

We emphasize that we do not read the Hatch-Waxman Amendments to repeal other rights under the Copyright Act of copyright owners in SmithKline's circumstances. Even though such an owner cannot enforce its copyright against generic drug manufacturers who are required by the Hatch-Waxman Amendments to copy labeling and who do no more than that, it still retains a copyright, if otherwise valid, in the label and might well pursue copyright claims against potential infringers in other circumstances, *e.g.*, use of the copyrighted material in non-labeling advertisements.

(Cont'd)

at 54 (1976) ("There is no intention whatever to narrow the scope of the subject matter now characterized in section 5(k) as 'prints and labels used for articles of merchandise.' "))), it has been recognized that the "danger lurking in copyright protection for labels is that the tail threatens to wag the dog — proprietors at times seize on copyright protection for the label in order to leverage their thin copyright protection over the text . . . on the label into a monopoly on the typically uncopyrightable product to which it is attached." *Id.* § 2.08[G][2], at 2-138. "Used in that fashion, the copyright serves 'primarily as a means of harassing competitors,' and thus fails 'nine times out of ten.' " *Id.* at 2-139. Here, although the labeling at issue is more creative than that in the "familiar" commercial labeling cases, *see Sassafras*, 889 F. Supp. at 345, SmithKline's copyright claim is arguably weaker than even the typical commercial labeling case, because the copyrighted text was submitted to obtain FDA approval and consequent market exclusivity.

Because recognition of SmithKline's claim here would severely undermine the Hatch-Waxman Amendments while its dismissal would not impair the copyright laws, we affirm and direct dismissal of SmithKline's complaint for failure to state a claim.[6] The stay is lifted forthwith.

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6. Even though SmithKline cannot enforce its copyrights against generic drug manufacturers who are required by the FDA to copy its labeling pursuant to the Hatch-Waxman Amendments, SmithKline retains its copyright in the user's guide and audiotape. SmithKline might well pursue copyright claims against potential infringers in other circumstances, *e.g.*, use of the copyrighted material in non-labeling advertisements.

APPENDIX B — MEMORANDUM DECISION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED DECEMBER 22, 1999

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

99 Civ. 9214 (DC)

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Plaintiff,

– against –

WATSON PHARMACEUTICALS, INC., *et al.*,

Defendants.

MEMORANDUM DECISION

* * *

CHIN, D. J.

On September 10, 1999, I issued a memorandum decision granting the motion of plaintiff SmithKline Beecham Consumer Healthcare, L.P. ("SmithKline") for a preliminary injunction enjoining defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. (collectively, "Watson") from marketing a generic version of SmithKline's nicotine gum

with an instructional booklet and audio tape "strikingly or substantially similar" to SmithKline's instructional booklet and audio tape. As a consequence of my preliminary injunction, Watson was unable to proceed with its "launch" of its product.

Watson now moves to vacate the preliminary injunction. For the reasons set forth below, Watson's motion is granted and the preliminary injunction is dissolved. Watson may proceed with the marketing of its generic version of a nicotine gum.

STATEMENT OF THE CASE

A. *The Facts*

The facts are set forth in detail in my Memorandum Decision dated September 10, 1999, *see SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc.*, 63 F. Supp. 2d 467 (S.D.N.Y. 1999), as modified by my Order dated September 16, 1999 (and docketed September 20, 1999). They may be summarized as follows:

SmithKline manufactures Nicorette nicotine polacrilex gum ("Nicorette"), an over-the-counter product for smokers seeking to quit smoking. Nicorette is sold with a "stop smoking plan" that features a user's guide (the "Guide") and an audio tape (the "Tape"). The Guide and Tape are copyrighted, creative materials. The Guide features graphics and drawings and the Tape features music and actors engaging in dialogue. The Guide and Tape are instructional materials that seek to encourage and guide smokers through

the process of reducing their dependence on nicotine to help them in their efforts to give up smoking.

Watson manufactures a generic version of Nicorette, to be sold as "Nicotine Gum" or "nicotine polacrilex." Watson's nicotine gum product is intended to compete directly with Nicorette, and Watson received approval from the Food and Drug Administration (the "FDA") earlier this year to market its product with a user guide and audio tape virtually identical to SmithKline's Guide and Tape. Watson had started shipping its product to retailers in late August when SmithKline commenced this action for copyright infringement to enjoin Watson's alleged willful and infringing copying of the Guide and Tape. As a result of the Court's preliminary injunction, Watson was unable to proceed with the marketing of its product.

B. ***The FDA's Involvement***

Watson's principal defense to the claim of copyright infringement is that its user guide and audio tape were part of the "labeling" approved by the FDA. Watson points out that the Federal Food, Drug, and Cosmetic Act (the "FFDCA") requires that the "labeling" for a generic drug be "the same as" the labeling approved for the "listed," or brand name, drug, 21 U.S.C. §355(j)(2)(A)(v), and notes that the FDA regulations broadly define "labeling" to include "all written, printed, or graphic matter" as well as "booklets" and "sound recordings." 21 C.F.R. §§ 1.3(a), 202.1(1)(2).

The FDA has taken varying, inconsistent positions on whether Watson's instructional materials must be identical

to SmithKline's materials. During the approval process for its nicotine gum, Watson initially submitted proposed text for an audio tape substantially different from the text of the SmithKline Tape. The FDA rejected the proposed text, advising Watson in a letter dated April 16, 1998 as follows:

> The text for your proposed audio is not the same as that for the reference listed drug, Nicorette. . . . Please revise your tape text to be in accord with that of Nicorette.

(9/1/99 DelGaudio Decl., Ex. C, at ¶ 5).

Watson thereafter revised its materials to be "in accord" with SmithKline's materials, and submitted a proposed user guide and audio tape virtually identical to SmithKline's Guide and Tape. On March 19, 1999, the FDA approved Watson's proposed "labeling." (9/1/99 DelGaudio Decl., at ¶ 17).

In late 1998 and early 1999, SmithKline raised certain concerns with the FDA regarding the use of instructional materials by sponsors of generic versions of Nicorette. In response, the FDA wrote SmithKline on March 15, 1999, explaining that:

> A sponsor of a generic nicotine smoking cessation aid will likewise be expected to provide appropriate behavioral support materials in each package or product. Because there is no single formula that is effective for every committed quitter, a sponsor will have *some discretion* to

> design appropriate support materials to enhance smoking cessation success rates.

(Weil Gotshal's 9/10/99 Letter to the Court, Ex. 1 at 2) (emphasis added). Although the FDA initially advised the Court that it had faxed an "advance copy" of this letter to Watson on March 13, 1999, the FDA later advised the Court that it had not done so. (FDA's 9/9/99 Letter to the Court at 2; FDA's 9/13/99 Letter to the Court). The FDA reported, however, that it had specifically advised Watson by telephone on March 11, 1999 that "the 'same labeling' requirement did not require that the generic's behavioral support materials be identical to the innovator's materials." (FDA's 9/9/99 Letter to the Court at 2).

The FDA confirmed to the Court, in its September 9, 1999 letter, that:

> generic sponsors, like all other sponsors of nicotine-based smoking cessation aids, have discretion to design their own audio support materials. . . . [No] formula for the behavioral support materials is effective for every person attempting to quit smoking. While the [FDA] has requested that sponsors include audiotapes and other behavioral support materials, and reviews such materials prior to authorizing marketing, the [FDA] does not approve the specific words or approach taken. Rather, it is the more general concept of providing quitters with a variety of useful support materials that the [FDA] has required.

(FDA's 9/9/99 Letter to the Court at 1-2). Hence, the FDA represented to the Court that it reviewed these support materials not for "specific words or approach," but for "concept." The FDA clearly was suggesting to the Court that sponsors of generic nicotine-based smoking cessation aids would have "discretion" to design their own materials. Moreover, the FDA represented to the Court that it had advised both Watson and SmithKline, the former by telephone and the latter by letter, of its position months earlier.

C. *Watson's Efforts To Revise Its Instructional Materials*

Based on the FDA's representation that "the 'same labeling' requirement did not require that the generic's behavioral support materials be identical to the innovator's materials," I concluded that the FDA would have permitted Watson to use a user's guide and audio tape that deviated to some extent from SmithKline's materials, *i.e.*, that Watson would have been permitted to use materials that were comparable to SmithKline's materials but that were sufficiently different in wording and otherwise to avoid copyright concerns. Based on the FDA's representation that it had advised Watson of this position in March 1999, I also concluded that Watson should have made more of an effort to obtain FDA approval of different language for its user guide and audio tape.

As a consequence, I issued my preliminary injunction, finding that the equities weighed in favor of SmithKline. In an order dated September 17, 1999, I urged the FDA "to use all reasonable effort to work with Watson to develop

acceptable, but different, instructional materials as quickly as possible."

Thereafter, Watson revised its instructional materials in an effort to address the copyright concerns. The new materials were comparable, but not identical, to SmithKline's materials. On September 22, 1999, Watson submitted the revised materials to the FDA for its approval.

D. *The FDA's Decision*

On November 23, 1999, the FDA issued a decision rejecting Watson's revised user's guide. The FDA, however, advised Watson that it would approve a revised version of Watson's "previously approved labeling," *i.e.*, the virtually identical user's guide previously approved by the FDA. The FDA approved "the graphics, layout, and design" of the newly revised user's guide, but it wanted Watson to return to the text of the previously approved user guide. The FDA marked up a copy of the previously approved user guide, bracketing certain portions, and explained:

> Please note that non-bracketed text should remain identical to your [previously] approved labeling. Text in brackets may be substituted with new text or deleted entirely (where appropriate). . . . Where text is substituted, it should be similar to the original in tone, content and length.

(Howrey & Simon's 12/1/99 Letter to the Court, Ex. C).

Appendix B

The bracketed guide shows that Watson was given very little leeway to deviate from the previously approved user guide. For example, one page was marked up as follows:

> **[SO YOU DECIDED TO QUIT]**
> [Congratulations!] Your decision to stop smoking is an important one. That's why you've made the right choice in choosing Nicotine Polacrilex Gum (pronounced "nik'-ah-teen poh-lah-cry'-lex gum").
>
> Your own chances of quitting smoking depend on how much you want to quit, how strongly you are addicted to tobacco, and how closely you follow a quitting program like the one that comes with Nicotine Polacrilex Gum.
>
> **QUITTING SMOKING IS HARD!** If you've tried to quit before and haven't succeeded, don't be discouraged! Quitting isn't easy. It takes time, and most people try a few times before they are successful. The important thing is to try again until you succeed. This User's Guide will give you support as you become a non-smoker. It will answer common questions about Nicotine Polacrilex Gum and give tips to help you stop smoking, and should be referred to often.
>
> **WHERE TO GET HELP.** You are more likely to stop smoking by using Nicotine Polacrilex Gum with a support program that helps you break your smoking habit. There may be support groups in your area for people trying to quit. Call your local

chapter of the American Lung Association, American Cancer Society or American Heart Association for further information. Toll free numbers are printed on the [Wallet Card] on the back cover of this User's Guide. If you find you cannot stop smoking or if you start smoking again after using Nicotine Polacrilex Gum, remember breaking this addiction doesn't happen overnight. You may want to talk to a health care professional who can help you improve your chances of quitting the next time you try Nicotine Polacrilex Gum or another method.

LET'S GET ORGANIZED. Your reason for quitting may be a combination of concerns about health, the effect of smoking on your appearance, and pressure from your family and friends to stop smoking. Or maybe you're concerned about the dangerous effect of second-hand smoke on the people you care about.

(Howrey & Simon's 12/1/99 Letter to the Court, Ex. C at 7). In other words, as a hand-written note on the bottom of the page explained, the FDA was permitting Watson to change or delete the text in only three bracketed places.[1] The balance of the page had to remain exactly the same.

The FDA thus determined that Watson had to copy verbatim substantially all of the text used in the SmithKline

1. The FDA later explained that it had intended to bracket all the boldfaced headings on the page, but had inadvertently failed to do so. (12/8/99 Tr. at 14).

Guide. In addition, the FDA determined that parts of Watson's audio tape had to be copied word for word from SmithKline's Tape and that certain parts could be different, provided the same essential concepts were conveyed.

The FDA — which is not a party in this case — was invited to and did attend a conference with the Court on December 8, 1999. The Court asked the FDA to "revisit" the question of whether portions of Watson's proposed user's guide could be rewritten to change the text "a little bit" to address the copyright concerns. (12/8/99 Tr. at 14).

On December 15, 1999, the FDA wrote the Court to advise that it had "decline[d] to change its approach to Watson's labeling." (FDA's 12/15/99 Letter to the Court at 1). The FDA advised the Court that because it "ha[d] never been directed by Congress to consider potential copyright rights in approving generic drug labeling," it would not take copyright considerations into account in this case. (*Id.* at 5).

The same day, the FDA issued a supplemental decision with respect to Watson's labeling requirements. (DX D). It requested certain limited changes to the user guide and a number of changes with respect to the audio tape. The FDA otherwise adhered to its decision to require Watson to copy verbatim most of the SmithKline Guide.

Hence, Watson will have FDA-approved labeling for its nicotine gum product once it makes the final changes requested by the FDA. Unless Watson uses this FDA-approved labeling (or some other FDA-approved labeling), Watson cannot market its product. On the other hand, in view

of the FDA's determination, it appears that Watson cannot market its product without using instructional materials that indeed are identical in substantial respects to SmithKline's copyrighted materials.

DISCUSSION

In my September 10, 1999 Memorandum Decision, I concluded that SmithKline had demonstrated the threat of irreparable harm in the absence of a preliminary injunction. I concluded also that SmithKline had not demonstrated a likelihood of success on the merits, but that it had demonstrated the existence of sufficiently serious questions going to the merits to make them a fair ground for litigation. Finally, I found that a balancing of the hardships tipped decidedly in SmithKline's favor. *SmithKline*, 63 F. Supp. 2d at 470-73; *see Polymer Tech. Corp. v. Mimran*, 37 F.3d 74, 77-78 (2d Cir. 1994).

On this motion to vacate the preliminary injunction, and upon reviewing the current record, I adhere to my conclusions that SmithKline has demonstrated irreparable harm and the existence of sufficiently serious issues going to the merits to make them a fair ground for litigation. I do so for the reasons set forth in my September 10, 1999 Memorandum Decision. I also adhere to the conclusion that SmithKline has not demonstrated a likelihood of success on the merits. Indeed, for the reasons discussed below, I am now persuaded that SmithKline is unlikely to succeed on the merits, at least in terms of its claim for injunctive relief.

Appendix B

The principal question presented by Watson's motion is whether, in view of the changes in the circumstances since I issued the preliminary injunction, a balancing of the hardships still tips decidedly in SmithKline's favor. I conclude that it does not.

First, the FDA has now made its position clear. Although it had previously suggested to the parties and the Court that it would take copyright considerations into account, that generic sponsors had a certain amount of discretion in fashioning behavioral support materials, and that instructional materials of a generic sponsor did not have to be identical to those of the innovator, the FDA has now made it clear that Watson cannot market its generic product without using labeling substantially similar to SmithKline's materials. Hence, the leeway that the Court was led to believe existed in fact does not exist.

Second, Watson has now made significant efforts to revise its materials to address the copyright concerns. Acting on the FDA's representations that it would be receptive to non-identical materials, Watson revised its materials and resubmitted them to the FDA. The FDA rejected those materials and there is little more that Watson can do in this respect. Moreover, the revised materials are now significantly more different from SmithKline's materials. For example, the user guide features a new layout and graphics and is designed as a package insert rather than as a booklet. Watson represents that the music and actors on the audio tape are different, and the transcript of the audio tape shows that the instructions are presented in a different format and factual setting.

Third, Watson has been severely prejudiced by the FDA's actions. More than three months have passed as Watson toiled in vain to revise its materials. Yet, those materials have been rejected, and Watson has now been placed in a position where it cannot market its product without violating the Court's preliminary injunction. *See* 21 U.S.C. § 355(a) ("No person shall introduce . . . any new drug, unless an approval of an . . . [abbreviated new drug application] is effective with respect to such drug.").

Fourth, the public has a stake in this controversy. The public can only benefit from the appearance in the market of a less expensive, generic alternative to Nicorette. While the public also has an interest in the integrity of copyrights, at this juncture I believe that the public's interest in the availability of a generic alternative to Nicorette outweighs its interest in the protection of the copyrights of a company that has not only enjoyed a monopoly for some fifteen years, but that surely knew that someday a generic version of its product would hit the market. Moreover, although money damages are not likely to fully compensate SmithKline for its injuries, the public's interest in the protection of copyrights can be vindicated to some degree by an award of money damages.

SmithKline argues that Watson has the option of asserting a claim under the Administrative Procedure Act against the FDA, either in this case or in a new action. *See also* 21 U.S.C. § 355(h) (covering appeals from decisions of the FDA denying applications for approval of new drugs). Such a claim might have merit, as the FDA's conduct in this case has indeed been perplexing. It shifted its position in a

manner that has prejudiced Watson. It refuses now to take into account copyright considerations, when it has previously suggested that it ought to take copyrights considerations into account. It determined first that Watson's labeling had to be identical, then decided that it did not have to be identical, and then decided that it had to be identical in substantial respects, but permitted certain deviations, without providing any meaningful guidance as to what must be identical and what may be different. It seemingly refuses to acknowledge that the materials in this case are not just "labeling," but rather that they are instructional materials that do involve a certain amount of creativity. It lumps instructional, motivational materials into the same category as warnings and directions on dosages.[2] It refuses to permit Watson to express such basic concepts as "don't be discouraged," "quitting isn't easy," "it takes time," and "the important thing is to try again until you succeed" in different words, when these same ideas could be expressed in a manner that would protect the public health without violating SmithKline's copyrights. It surely has a duty to address the apparent conflict between the Copyright Act and the FFDCA.[3]

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2. At the same time, however, the copyrighted materials are instructional materials for a drug, and the FDA is of course rightfully concerned that consumers be properly instructed so that the product will be used in a safe and effective manner.

3. SmithKline also suggests that the Court rule that the FDA must take its copyrights into account. I am tempted, for it is difficult to understand how the FDA can simply ignore the public's interest in the protection of copyrights, and I would think that it is within the FDA's mandate to address the interplay between the Copyright Act and the FFDCA. The FDA, however, is not a party to this action.

Still, I do not believe that it would be just to continue to enjoin Watson from marketing its product based on the argument that it could bring suit against the FDA. Such a lawsuit would undoubtedly involve extensive delay, *see, e.g., Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1 (D.D.C. 1989) (dismissing suit brought by cosmetics manufacturer challenging FDA's determination that a product was a "drug" rather than a "cosmetic" under FFDCA, for failure to exhaust administrative remedies), and Watson would not be able to market its product in the meantime. Watson would also have to take positions in such a lawsuit that could conflict with the positions it has taken in this case. Indeed, it is conceivable that Watson would find itself arguing SmithKline's position in any such case, and as a manufacturer of generic drugs Watson surely would not want to argue that a national brand company's copyrights abrogate the FFDCA. Finally, of course, the outcome of any such litigation would be uncertain.

The fact is that no generic version of Nicorette is likely to reach the market anytime soon, unless SmithKline's arguments are rejected. If SmithKline is correct in its contention that its rights under the Copyright Act override Watson's rights and obligations under the FFDCA, in view of the FDA's current position, Watson would have to either successfully sue the FDA or persuade Congress to direct the FDA "to consider potential copyright rights in approving generic drug labeling."

As I have held, SmithKline has demonstrated that it will suffer irreparable harm if Watson is permitted to market its product using SmithKline's copyrighted Guide and Tape. In

view of the FDA's position, however, SmithKline's only remedy may be damages, in the nature of implied license fees, even though that remedy may not be an adequate one. Even if SmithKline is correct in its interpretation as to the interplay between the Copyright Act and the FFDCA, a court of equity is not likely to find that the public should be deprived of the alternative of a generic version of Nicorette.

CONCLUSION

The preliminary injunction entered in this case on September 20, 1999 is hereby dissolved. Watson may proceed with the marketing and distribution of its nicotine gum.

SO ORDERED.

Dated: New York, New York
December 22, 1999

s/ Denny Chin
DENNY CHIN
United States District Judge

Appendix B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

99 Civ. 9214 (DC)

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Plaintiff,

– against –

WATSON PHARMACEUTICALS, INC., *et al.*,

Defendants.

ORDER

CHIN, D.J.

For the reasons set forth in the Court's Memorandum Decision issued today, Watson's motion to modify the preliminary injunction issued in this case is hereby GRANTED and the preliminary injunction is hereby DISSOLVED to the extent that Watson is permitted to market and distribute its nicotine gum using the New Behavioral Materials.

SO ORDERED.

Dated: New York, New York
December 22, 1999

s/ Denny Chin
DENNY CHIN
United States District Judge

APPENDIX C — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED SEPTEMBER 17, 1999

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

99 Civ. 9214 (DC)

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Plaintiff,

– against –

WATSON PHARMACEUTICALS, INC., *et al.*,

Defendants.

ORDER

CHIN, D.J.

Defendants (collectively "Watson") seek a stay of this Court's preliminary injunction pending appeal and, alternatively, they ask that a bond be required in the amount of $20 million. The request for a stay is granted in part and denied in part. The bond is set at $1 million.

The request for a stay is denied to the extent the Court has enjoined Watson during the pendency of this action from selling or shipping its nicotine gum with a user guide or audiotape that are strikingly or substantially similar to SmithKline's Guide and Tape.

Appendix C

I have weighed the four factors to be considered on an application for a stay pending appeal. Watson has not made a strong showing that it is likely to succeed. The legal issues are complicated issues of first impression, and while serious issues exist to be litigated, I am not persuaded that Watson is likely to succeed on appeal. Moreover, as a factual matter, on the limited record before me, it is clear that the FDA would have entertained a user's guide and audiotape that were not identical to SmithKline's versions, and it is also clear that Watson made little effort to press the issue with the FDA.

The second and third factors essentially involve a balancing of the equities, and for the reasons set forth in my Memorandum Decision, I believe the equities tip decidedly in favor of SmithKline. In addition, Watson is not precluded from marketing or selling its nicotine gum; it merely must revise its user's guide and audiotape before doing so. I appreciate that this is not a simple or inexpensive matter; nonetheless, it is a process that Watson should have engaged in before it launched its product. As to the delay, while the Court does not have jurisdiction over the FDA in this case, as the FDA is not a party, the Court urges the FDA to use all reasonable effort to work with Watson to enable Watson to develop acceptable, but different, instructional materials as quickly as possible.

Finally, while the public does have a strong interest in having a generic version of the product available, it also has a strong interest in the preservation of copyrights. Again, Watson is not precluded from selling a generic nicotine gum. Moreover, as Watson notes, there are other competitors that may market a generic version of nicotine gum; presumably

these would be available to the public as well. In addition, the unrestricted copying of copyrighted materials, developed only with great effort and at great expense, purportedly at the behest of the FDA when the FDA has acknowledged that it would consider non-identical materials, would not be in the public interest.

A stay pending appeal, however, is granted as to my recall order until a motion for a stay can be heard in the Second Circuit, on the condition that Watson uses all reasonable effort — including advising its customers, if it has not already done so, that the Court has issued an injunction — to ensure that its product will not be sold with the instructional materials in question.

As to the bond, I will set the amount at $1 million. Of course, if a determination is later made that the bond was improperly issued, Watson will not be limited to $1 million in damages if it can prove damages in excess thereof.

SO ORDERED.

Dated: New York, New York
September 17, 1999

s/ Denny Chin
DENNY CHIN
United States District Judge

APPENDIX D — ORDER FOR PRELIMINARY INJUNCTION OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED SEPTEMBER 17, 1999

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

99 Civ. 9214 (DC)

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Plaintiff,

v.

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., AND CIRCA PHARMACEUTICALS, INC.,

Defendants.

ORDER FOR PRELIMINARY INJUNCTION

Plaintiff SmithKline Beecham Consumer Healthcare, L.P. having moved for a preliminary injunction pursuant to Fed. R. Civ. P. 65 and now upon reading and filing the Summons and Complaint dated August 26, 1999; the Order to Show Cause for a Preliminary Injunction dated August 27, 1999 and the supporting Affidavits of Helene D. Jaffe sworn to on August 27, 1999, George Quesnelle sworn to on August 24, 1999, and Dr. Robert Grayson sworn to on

Appendix D

August 24, 1999; Plaintiff's Memorandum of Law in Support of its Application for a Preliminary Injunction dated August 27, 1999; the Memorandum in Opposition to SmithKline Beecham Consumer Healthcare's Motion for Temporary Restraining Order dated September 2, 1999 and the accompanying Declarations of Robert C. Denicola sworn to on September 1, 1999, Fred Wilkinson sworn to on September 2, 1999, and Joyce Anne DelGaudio sworn to on September 1, 1999; Plaintiff's Application for a Temporary Restraining Order and the accompanying Affidavits of Raymond J. DeRise sworn to on September 1, 1999 and Bruce S. Meyer sworn to on September 1, 1999; the Supplemental Memorandum in Opposition to SmithKline Beecham Consumer Healthcare's Motion for Preliminary Injunction dated September 3, 1999; the Reply Memorandum of Law in Further Support of Plaintiff's Application for a Preliminary Injunction dated September 8, 1999 and the accompanying Affidavits of Professor Arthur R. Miller sworn to on September 7, 1999 and George Quesnelle sworn to on September 7, 1999 and the Declarations of Stuart M. Pape sworn to on September 8, 1999 and Sandra Wilbur sworn to on September 8, 1999; the Declaration of Gordon R. Johnston sworn to on September 7, 1999; the letter to the Court from Janet Woodcock, M.D., dated September 9, 1999; the letter to the Court from Helene D. Jaffe, dated September 10, 1999; the letter to the Court from Barry S. White, dated September 10, 1999; upon the hearing of oral argument by the parties on September 9, 1999, and upon review of the exhibits marked at that hearing; and in accordance with this Court's Memorandum Decision dated September 10, 1999 (attached hereto at Tab A), and upon the follow-up submissions and the Court's Order of 9/16/99 it is hereby:

Appendix D

ORDERED, that pending a final determination of the matter, Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. ("Watson"), their directors, officers, servants, employees, agents and all persons in active concert or participation with them are:

1. enjoined, pending entry of final judgment, from further sale and/or shipment of Nicotine Polacrilex Gum, USP with a user's guide, audiotape, or other package insert "strikingly or substantially similar" to SmithKline's Nicorette user's guide and audiotape, including but not limited to the materials submitted to the Court as Plaintiff's Exhibits 1 and 6;

2. ordered to take all steps necessary to recall all Nicotine Polacrilex Gum, USP that has already been shipped, including but not limited to removing the product from retail shelves, commencing immediately and to be completed no later than ten (10) days following issuance of this injunction order;

3. ordered to take all steps necessary to ensure that no Nicotine Polacrilex Gum, USP that has already been shipped reaches retail shelves; and

4. required to file with this Court and serve upon SmithKline, within ten (10) days after issuance of this injunction order, a report in writing and under oath, setting forth in detail the manner and form in

which Watson has complied with the relief ordered therein; and

IT IS FURTHER ORDERED, that SmithKline Beecham Consumer Healthcare, L.P. shall post a bond in the amount of $1,000,000.

Paragraph 2 above is stayed pending a decision by the Second Circuit on a motion for a stay pending appeal, as set forth in the Court's Order of 9/17/99, as long as said motion is filed promptly.

Dated: New York, New York
September 17, 1999

s/ Denny Chin
Hon. Denny Chin
United States District Judge

APPENDIX E — MEMORANDUM DECISION OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED SEPTEMBER 10, 1999

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

99 Civ. 9214 (DC)

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Plaintiff,

– against –

WATSON PHARMACEUTICALS, INC., *et al.*,

Defendants.

MEMORANDUM DECISION

* * *

CHIN, D. J.

In this case of first impression, plaintiff, the manufacturer of a national brand nicotine gum, seeks to enjoin defendants from marketing a competing generic version of the nicotine gum with "labeling" — an instructional booklet and audio tape — that is "strikingly or substantially similar" to plaintiff's "labeling." Defendants' principal defense to the claim of copyright infringement is

that they were required by the Food and Drug Administration (the "FDA") to use "labeling" that was "the same as" the labeling approved for use with the national brand. Plaintiff moves for a preliminary injunction.

For the reasons that follow, the motion for a preliminary injunction is granted. The following constitute my findings of fact and conclusions of law.

FINDINGS OF FACT

Plaintiff SmithKline Beecham Consumer Healthcare, L.P. ("SmithKline") manufactures Nicorette nicotine polacrilex gum ("Nicorette"), an over-the-counter product for smokers seeking to quit smoking. Nicorette is sold with a "stop smoking plan" that features a user's guide (the "Guide") and an audio tape (the "Tape"). The Guide and Tape are copyrighted, creative materials. The Guide features graphics and drawings and the Tape features music and actors engaging in dialogue. The Guide and Tape are instructional materials that seek to encourage and guide smokers through the process of reducing their dependence on nicotine to help them in their efforts to give up smoking. SmithKline spent more than one million dollars developing the Guide and Tape, in a process spanning several years. (First Quesnelle Aff. ¶ 11).

Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. (collectively, "Watson") manufacture a generic or private label version of Nicorette, sold as "Nicotine Gum" or "nicotine polacrilex, USP." Watson's nicotine gum product

is intended to compete directly with Nicorette. Watson received approval from the FDA earlier this year to market the product, and it had planned originally to "launch" the product on August 1, 1999. (First Wilkinson Decl. ¶ 10).

The Watson product is accompanied by a user guide and audio tape that are virtually identical to SmithKline's Guide and Tape. The text of the two tapes is identical (except for the product names). Although some of the music on the two tapes is different, some of the music is identical. The text of the two user guides is also identical (except for the names). The graphics in the Watson guide have been changed from the graphics in SmithKline's Guide, but only slightly; for example, instead of the father and a dog found in the SmithKline Guide drawing, a mother and a cat appear in the Watson version.

SmithKline commenced this action for copyright infringement to enjoin Watson's alleged willful and infringing copying of the Guide and Tape. Watson's principal defense is that its user guide and audio tape were part of the "labeling" approved by the Food and Drug Administration (the "FDA"). Watson contends that the Federal Food, Drug, and Cosmetic Act (the "FFDCA") requires that the labeling for a generic drug be "the same as" the labeling approved for the "listed," or brand name, drug, 21 U.S.C. § 355(j)(2)(A)(v), and notes that the FDA regulations broadly define "labeling" to include "all written, printed, or graphic matter" as well as "booklets" and "sound recordings." 21 C.F.R. §§ 1.3(a), 202.1(l)(2). Watson relies heavily on the fact that during the approval process for its nicotine gum, when it submitted proposed text for an audio tape

substantially different from the text of the SmithKline Tape, the FDA rejected the proposed text, advising Watson in a letter dated April 16, 1998 as follows:

> The text for your proposed audio is not the same as that for the reference listed drug, Nicorette. . . . Please revise your tape text to be in accord with that of Nicorette.

(DelGaudio Decl., Ex. C).

On July 28, 1999, SmithKline obtained a copy of Watson's guide for its nicotine gum product from the FDA. It did not obtain a copy of a transcript of Watson's audio tape from the FDA until August 24, 1999. (First Quesnelle Aff. ¶ 32). SmithKline commenced this lawsuit two days later, on August 26, 1999.

The same day that suit was filed, unbeknownst to SmithKline, Watson commenced shipments of its nicotine gum product to its retailer customers. Shipments continued through August 28, 1999, and a total of some twenty-two million pieces of gum were shipped by "Next Day Air." (Wilkinson Decl. ¶ 10).

On August 27, 1999, the day after suit was filed, I issued an order directing Watson to show cause why a preliminary injunction should not be issued enjoining it, during the pendency of this action, from selling or shipping its nicotine gum with a user's guide, audio tape, or other packaging insert "strikingly or substantially similar" to SmithKline's Guide and Tape. SmithKline did not request a temporary restraining order at that time. The motion for a preliminary injunction was made returnable September 15, 1999.

Appendix E

On August 30, 1999, Watson announced that it had "launched" its nicotine gum product. SmithKline learned on September 1, 1999 that Watson had shipped product to four customers (retail chains). (9/2/99 Tr. at 2). Concerned that Watson had commenced or was about to commence shipments, SmithKline requested a temporary restraining order. At a conference on September 2, 1999, Watson agreed to refrain, pending a hearing on SmithKline's motion for a preliminary injunction, from making any additional shipments, without prior notice, and it also agreed to contact its customers to advise them not to place any of Watson's product on shelves pending the hearing.

The return date for the preliminary injunction motion was accelerated to yesterday, September 9, 1999, and a hearing was held. Watson agreed to continue to refrain from making shipments without prior notice and to use best efforts to prevent any sales of its product for a week while I considered SmithKline's motion.

Following the hearing, the FDA submitted a letter to the Court yesterday afternoon (the "FDA Letter") to "provide some context and clarify its position." The FDA explained that while it did initially advise Watson that the generic version of Nicorette had to have the same labeling, later communications from the FDA to Watson clarified that position to address the concern that the Nicorette labeling might be subject to copyright protection. The FDA Letter reported that the FDA had explained to Watson in March 1999 the FDA's view that:

> generic sponsors, like all other sponsors of nicotine-based smoking cessation aids, have

> discretion to design their own audio support materials. As the [FDA] explained, no formula for the behavioral support materials is effective for every person attempting to quit smoking. While the [FDA] has requested that sponsors include audiotapes and other behavioral support materials, and reviews such materials prior to authorizing marketing, the [FDA] does not approve the specific words or approach taken. Rather, it is the general concept of providing quitters with a variety of useful support materials that the [FDA] has required.

The FDA Letter also explained that in March 1999 an FDA representative had explained to Watson in a telephone conversation that "the 'same labeling' requirement did not require that the generic's behavioral support materials be identical to the innovator's materials."

In its papers and arguments presented to the Court in opposition to SmithKline's motion, Watson did not disclose any of these communications.[1]

DISCUSSION AND CONCLUSIONS OF LAW

To obtain a preliminary injunction, SmithKline must demonstrate (1) irreparable harm in the absence of the requested relief and (2) either (a) a likelihood of success on

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1. On the other hand, SmithKline was also made aware of the FDA's position, by letter dated March 15, 1999, but SmithKline failed to advise the Court of this communication.

the merits or (b) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in its favor. *See Polymer Tech. Corp. v. Mimran*, 37 F.3d 74, 77-78 (2d Cir. 1994).

A. *Irreparable Harm*

SmithKline has demonstrated that it will suffer irreparable harm if a preliminary injunction is not issued. In this Circuit, a prima facie case of copyright infringement normally gives rise to a presumption that the copyright owner will suffer irreparable harm. *See ABKCO Music, Inc. v. Stellar Records, Inc.*, 96 F.3d 60, 64 (2d Cir. 1996). Here, there is no dispute that Watson copied, almost verbatim, the text of SmithKline's copyrighted Guide and Tape. If Watson's interpretation of the FFDCA and the FDA regulations is wrong and it did infringe on SmithKline's copyrights, then SmithKline presumptively suffered irreparable harm.

Moreover, presumptions aside, the record contains concrete evidence of SmithKline's irreparable harm. SmithKline spent several years and more than one million dollars developing a creative Guide and Tape that are an important part of the Nicorette product and an important component of the brand image that SmithKline has sought to create. The introduction into the market of virtually identical user guides and instructional tapes is likely to confuse consumers and threaten consumer goodwill. *See Tom Doherty Assocs., Inc. v. Saban Entertainment, Inc.*, 60 F.3d 27, 37 (2d Cir. 1995); *Fisher-Price, Inc. v. Well-Made Toy Mfg. Corp.*, 25 F.3d 119, 124 (2d Cir. 1994). While

it is true, as Watson argues, that there is no separate market for the guides and tapes, the guides and tapes are a critical part in the marketing of the product and their role cannot be minimized. SmithKline will suffer irreparable harm if they are wrongfully copied.

B. *The Merits*

As to the merits, the parties agree that this is a case of first impression. They are aware of no case involving copyrighted, instructional "labeling" of the kind at issue here, where the manufacturer of a generic drug was required by the FDA to use instructional "labeling" — a guide book or audio tape — that was "the same as" the previously FDA-approved instructional labeling of the "listed," or national, brand. In view of the arguments presented, and in the limited time I have had to consider the issues, I cannot conclude that SmithKline has demonstrated a likelihood of success on the merits.[2]

Clearly, however, at a minimum SmithKline has demonstrated sufficiently serious issues going to the merits to make them a fair ground for litigation. The case presents significant issues involving the interplay between the Copyright Act and the FFDCA. SmithKline argues forcefully that the FFDCA cannot have the effect of repealing the copyright laws and that the FFDCA cannot nullify its rights under the copyright laws. *See Watt v. Alaska*, 451 U.S. 259, 267 (1981) (noting that courts must read two federal statutes "to give effect to each if [it] can do so while preserving their

2. As a factual matter, however, the FDA Letter strongly undercuts Watson's factual premise for its position.

sense and purpose"); *cf. Practice Management Info. Corp. v. American Med. Ass'n*, 121 F.3d 516 (9th Cir.) (use by Health Care Financing Administration of copyrighted medical procedure code in Medicaid reimbursement regulations did not render copyright invalid), *cert. denied*, 118 S. Ct. 339 (1997), *opinion amended by* 133 F.3d 1140 (9th Cir.), *cert. denied*, 118 S. Ct. 2367 (1998); *CCC Information Servs., Inc. v. MacLean Hunter Mkt. Reports, Inc.*, 44 F.3d 61 (2d Cir. 1994) (copyrighted compendium of used car valuations did not fall into public domain merely because the information was incorporated into insurance laws of several states), *cert. denied*, 516 U.S. 817 (1995). Meritorious issues exist as to the meaning of "the same as," particularly in the context of creative instructional materials, and as to whether Watson's instructional materials could have been drafted to comply with the FDA regulations without violating SmithKline's copyrights.

C. *Balancing of the Hardships*

Finally, I find that a balancing of the hardships tips decidedly in SmithKline's favor.

As noted, SmithKline spent more than one million dollars and several years developing its Guide and Tape. These are creative, instructional materials that are intended to assist smokers in their struggle to stop smoking. They are relied upon by consumers, and the Guide and Tape are important to SmithKline's efforts to market Nicorette. Indeed, millions of boxes of Nicorette have been sold with the Guide and Tape, and SmithKline has spent in excess of $200 million in bringing Nicorette to market and developing

a brand image. (Supp. Quesnelle Aff. ¶ 9). Moreover, the consumer confusion and loss of goodwill that would result from the use by Watson of a user's guide and audio tape virtually identical to SmithKline's Guide and Tape would be significant. In the absence of a preliminary injunction, Watson — a direct competitor — would be able to misappropriate SmithKline's copyrighted creative materials to reach the same target consumers.

On the other hand, Watson also would suffer substantial financial losses if its launch of the product is delayed and it is required to revise its guide and tape. SmithKline has enjoyed many years of exclusivity, and Watson has now been given the right, after much effort, to market a generic version of Nicorette. Finally, the availability of a generic option will benefit consumers.

On balance, I find that the equities weigh decidedly in favor of SmithKline. Any harm that Watson would suffer by the issuance of a preliminary injunction is largely the result of its own doing. When suit was filed, Watson apparently had just started shipping product, and the "harm" then would have simply been a delay in the launch. Yet, rather than mitigate its damages, Watson chose to go ahead and continue to ship some twenty-two million pieces of gum even though it was aware of the lawsuit. *See Cherry River Music Co. v. Simitar Entertainment, Inc.*, 38 F. Supp. 2d 310, 323 (S.D.N.Y. 1999) (recall order was appropriate in part because party opposing motion for preliminary injunction "deliberately sailed in harm's way" by continuing to manufacture and ship infringing product after receiving cease-and-desist letter).

In addition, Watson clearly should have made more of an effort to address the copyright issue with the FDA. (*See* Pape Decl. ¶¶ 5, 6). Watson's claim that it was forced by the FDA to copy the text of the SmithKline Guide and Tape verbatim is, at minimum, a gross exaggeration, as the FDA Letter shows that the FDA explained to Watson in March 1999, both orally and in writing, that the "same labeling" requirement did not require the generic "behavioral support materials" to be "identical" to the "innovator's" materials.[3] There are many different ways that a manufacturer can express the ideas used in SmithKline's Guide and Tape,[4] and Watson certainly could have proposed some different language in its user guide and tape to avoid problems of copyright infringement. Yet, Watson made no effort to do so, apparently because it was content to copy — verbatim — SmithKline's Guide and Tape, knowing that they were copyrighted.

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3. Watson submitted an affidavit from its Director of Regulatory Affairs and Product Development, which purports to lay out the history of the FDA's approval of the labeling for the nicotine gum product. The affidavit does not, however, set forth the communications between the FDA and Watson — which include a telephone conversation between the Director and an FDA representative — whereby Watson was advised by the FDA that "the same as" did not mean "identical." Rather, Watson took the position in its papers submitted to this Court that it was a "fact" that "the [FDA] required Watson to use *precisely* the labeling that it is using." (Def. Mem. In Opp. at 2) (emphasis added).

4. In the nicotine "patch" market, which is somewhat analogous because the "labeling" for patches also includes instructional materials and user guides, the materials vary greatly in terms of format, layout, typeface, and text. (First Quesnelle Aff. ¶ 26 & Exs. C, D, E).

Appendix E

The harm suffered by both SmithKline, in the absence of a preliminary injunction, and Watson, on the granting of a preliminary injunction, would be compensable, to some degree, by monetary damages. But Watson's harm (the loss of sales revenue) is more easily recompensed monetarily than SmithKline's harm (the loss of goodwill and consumer confusion), and, as noted, Watson's harm is largely the result of its own actions.

CONCLUSION

Accordingly, SmithKline's motion for a preliminary injunction is granted, and defendants are hereby enjoined, during the pendency of this action, from selling or shipping its nicotine gum with a user's guide, audio tape, or other packaging insert "strikingly or substantially similar" to SmithKline's Guide and Tape. Defendants are also hereby ordered to recall any nicotine gum packaged with a user's guide, audio tape, or other insert "strikingly or substantially similar" to SmithKline's Guide and Tape.

SmithKline shall submit a proposed order, on notice, within five days hereof. SmithKline's request for attorneys' fees and sanctions will be deferred until after the litigation has been resolved on the merits.

Dated: New York, New York
September 10, 1999

s/ Denny Chin
DENNY CHIN
United States District Judge

APPENDIX F — LETTER FROM JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, TO THE HONORABLE DENNY CHIN DATED SEPTEMBER 9, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 9, 1999

To: The Honorable Denny Chin

The Court has asked for the Food and Drug Administration's ("FDA") views on the copyright infringement lawsuit between SmithKline Beecham ("SmithKline") and Watson Pharmaceuticals ("Watson"). It is agency policy not to take a position on the merits of intellectual property disputes (patent, trademark, copyright) between entities that it regulates. However, it has come to the agency's attention that in a September 2, 1999, proceeding before this Court, an issue arose as to whether FDA had required the generic product to have labeling that is identical to that of the innovator's in spite of the fact that certain parts of the innovator's labeling may be subject to copyright protection. FDA files this submission to provide some context and clarify its position on this issue.

In April 1998 the Division of Labeling and Program Support (Office of Generic Drugs) within FDA's Center for Drug Evaluation and Research ("CDER"), sent a facsimile

to Watson stating that the generic version of the product must include the same audiotape as that included with the innovator's product. However, subsequent communications between the agency and Watson, and the agency and SmithKline, show that this communication to Watson taken alone did not fully, or with sufficient clarity, represent the agency's position.

In October 1998 and January 1999, SmithKline requested clarification from the Director of CDER on the issue of whether a generic sponsor of a nicotine policrilex gum product would be required to include with its product an audiotape that is identical to the audiotape included with SmithKline's version of the product. After carefully considering the matter, the agency outlined its position in a letter to SmithKline dated March 15, 1999 (Attachment 1). In that letter, the agency informed SmithKline that, in fact, generic sponsors, like all other sponsors of nicotine-based smoking cessation aids, have discretion to design their own audio support materials. As the agency explained, no formula for the behavioral support materials is effective for every person attempting to quit smoking. While the agency has requested that sponsors include audiotapes and other behavioral support materials, and reviews such materials prior to authorizing marketing, the agency does not approve the specific words or approach taken. Rather, it is the more general concept of providing quitters with a variety of useful support materials that the agency has required.

To ensure that Watson was informed of this position at the earliest possible date, the agency faxed Watson an advanced copy of the agency's analysis on March 13, 1999

(Attachment 2). The agency also called Joyce DelGaudio, Department of Regulatory Affairs at Watson, and explained that the "same labeling" requirement did not require that the generic's behavioral support materials be identical to the innovator's materials. It was explained that a generic's materials, instead, needed to contain the same essential elements in a comparable format (Attachment 3, memorandum of teleconference dated March 11, 1999).

When Watson submitted its proposed user's guide and audiotape after being informed of the agency's position on the regulatory issue, the agency approved Watson's materials under the Federal Food, Drug, and Cosmetic Act without taking a position on the potential copyright infringement issues.

Sincerely,

s/ Janet Woodcock
Janet Woodcock, M.D.
Director, Center for Drug Evaluation
and Research

Attachment

APPENDIX G — LETTER FROM KIM E. DETTELBACH, ASSOCIATE CHIEF COUNSEL, FOOD AND DRUG ADMINISTRATION, TO THE HONORABLE DENNY CHIN DATED DECEMBER 15, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

December 15, 1999

To: The Honorable Denny Chin

At a status conference on December 8, 1999, the Court asked FDA to review its approach to Watson Pharmaceutical's audiotape and User's Guide for nicotine polacrilex gum to determine whether greater differences between SmithKline's labeling and Watson's labeling could be permitted without violation of FDA's governing statute and regulations and without jeopardizing public health. The Court suggested that FDA consider allowing Watson to change the wording from that used by SmithKline where the same meaning is conveyed in order to limit or moot SmithKline's claims of copyright infringement and to hasten the marketing of Watson's product.

Appendix G

FDA has given serious consideration to the Court's suggestion. However, for the reasons expressed below, FDA declines to change its approach to Watson's labeling.[1]

As FDA informed the Court at the December 8 status conference, generic drug labeling is approved under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 201 et seq. That Act states that an abbreviated new drug application (commonly referred to as an "ANDA" or generic drug application) shall contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug . . . except for differences approved . . . because the new drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. 355(j)(2)(A)(v). FDA's regulations similarly state that labeling proposed for the drug product "must be the same as the labeling approved for the reference listed drug, except for changes required because . . . the drug product and the reference listed drug are produced or distributed by different manufacturers. Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling

1. As counsel represented to the Court at the December 8, 1999 status conference, although only the first bolded heading was bracketed in the November 23, 1999 letter, FDA will permit Watson to change all of the bolded headings in the User's Guide, as long as the headings substituted appropriately introduce the textual material to follow. This change is consistent with the review principles articulated below. Upon receipt of the FDA's November 23, 1999 letter, Watson submitted revised labeling to FDA. FDA has reviewed that labeling and on December 15, 1999 forwarded Watson its comments on the revised labeling.

revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or exclusivity under section 505(j)(4)(D) of the act." 21 C.F.R. 314.94(a)(8)(iv). Neither the statute, regulations, nor the legislative history expressly authorizes labeling changes based on an innovator's copyright.

While the statute defines labeling broadly to include a variety of material, including material that FDA does not review in advance and approve,[2] under FDA labeling regulations for over the counter drugs, wording for a number of categories of labeling information is subject to the Agency's review and approval as part of the drug approval process and generally cannot be changed thereafter by the innovator or the generic firm. For over the counter drug products[3], these categories include: (1) product description; (2) principal intended pharmacological action of the drug product; (3) indications and usage (including limitations on effectiveness and descriptions of the kind, degree, and duration of improvement to be expected); (4) warnings,

2. The statute defines "labeling" broadly to include "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C.A. § 321(m).

3. Because the product at issue is an over-the-counter drug product, this discussion addresses labeling requirements for over-the-counter drug products. Labeling for prescription drug products is addressed separately in 21 C.F.R. § 201.57. Although 21 C.F.R. § 201.57 is not referenced specifically in the discussion that follows, the Agency's concerns expressed here apply with equal force in the prescription drug context.

precautions and contraindications including significant drug/food and drug/drug interactions; (5) common side effects and adverse reactions; and (6) directions for use (including dosage, administration, and overdosage). 21 C.F.R. § 201.66. Where labeling includes text that falls into these pre-approval review categories under 21 C.F.R. § 201.66, FDA has required the generic's labeling to be the same as that of the innovator except for the limited types of differences due to difference in manufacturer described in 21 C.F.R. § 314.94(a)(8)(iv). Consistent with the statute, regulations, and FDA's longstanding practice, this is the case even where it may be possible to convey the same essential information using different words.

FDA's November 23, 1999 letter to Watson reflects FDA's application of these governing statutory and regulatory principles. Watson's labeling review presented a situation in which (1) the innovator's labeling that Watson's labeling was required to be "the same as" was copyrighted by SmithKline and (2) SmithKline included labeling text of the type subject to FDA review and pre-approval and other additional labeling material in the same documents. Faced with this factual context, FDA applied its scientific judgment to identify text subject to agency review and approval under 21 C.F.R. § 201.66 and to separate it from other additional information and behavioral support that SmithKline provides committed quitters who purchase Nicorette gum starter kits. Where the labeling included text required to be reviewed and approved under in 21 C.F.R. § 201.66 (indications and usage, warnings, dosage and administration, etc.), Watson, like all generic drug applicants, was required to use nearly identical language (except for differences of the type

enumerated under 21 C.F.R. § 314.94(a)(8)(iv)). Consistent with the statute and regulations, this requirement was applied even where the language chosen by SmithKline and approved by FDA was colloquial and even where it was theoretically possible for different language to convey the same meaning. Where the labeling included additional information or content outside of the scope of 21 C.F.R. § 201.66 (*e.g.* specific relaxation tips, examples of strategies to fight temptation, music, graphics, actors or characters), however, Watson was given more discretion to use different words to convey the important concepts that FDA identified in a truthful, non-misleading presentation and a comparable format.

Though this approach of separating labeling subject to review and approval under 21 C.F.R. § 201.66 from other labeling included in Nicorette gum starter kits, and requiring the former category of labeling to be the same as that of the innovator except for differences of the type described in 21 C.F.R. § 314.94(a)(8)(iv), FDA has focused on the requirements of Waxman-Hatch for generic drug approvals and the FDA's mission to protect public health, while providing the generic some flexibility in addressing the copyright protections that SmithKline claims for its labeling. An alternate approach would require FDA, upon receiving a generic application, to (1) reexamine the words of innovator labeling reviewed and approved under 21 C.F.R. § 201.66 to determine which individual words have unique medical significance and cannot be changed, and (2) review the generic's proposed labeling to determine which substantially changed words or sentences can be substituted for the innovator's approved text without changing the labeling's

meaning or nuance. This would place an untenable administrative burden on FDA. Such a review process for generic drug labeling would force FDA medical officers to review each change from the innovator's labeling proposed by the generic to determine whether the approval of the innovator product supported the proposed change and to ensure that no unintentional difference in meaning is conveyed that might jeopardize safe or effective use of the product. Similarly, generic drug reviewers would be required to assess each proposed change to determine whether it gave the consumer or prescribing physician the misimpression that the generic drug had a therapeutic or marketing difference that is inconsistent with a generic drug approval. It would most certainly interfere with FDA's ability to process generic drug applications in a timely fashion.

While the Court has suggested that the copyright issues in this case may warrant a new approach to the "same labeling" requirement, FDA has never been directed by Congress to consider potential copyright rights in approving generic drug labeling. The generic drug approval process established in the Federal Food, Drug, and Cosmetic Act emphasizes the "sameness" of the generic and innovator drugs as a means to assure that the generic drug is as safe and effective as the innovator product. Product labeling is a crucial component in the safe and effective use of a drug. Permitting certain labeling changes because of copyright considerations in this case could set a precedent for permitting significant changes from an innovator's approved labeling text that go beyond the limited differences permitted under 314.94(a)(8)(iv), and may raise questions regarding the sameness of the innovator and generic drugs. Without

specific direction from Congress, FDA declines to interpret the generic drug labeling requirements in a way that may jeopardize its ability in the future to prevent other generic drug manufacturers from making significant changes to labeling approved under 21 C.F.R. § 201.66.

Thank you for the opportunity to present the Agency's views to assist the Court in understanding this important matter.

Sincerely,

s/ Kim E. Dettelbach
Kim E. Dettelbach
Food and Drug Administration
Associate Chief Counsel

APPENDIX H — REGULATION INVOLVED

21 C.F.R. § 201.66

CODE OF FEDERAL REGULATIONS
TITLE 21 — FOOD AND DRUGS
CHAPTER I — FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C — DRUGS: GENERAL
PART 201 — LABELING
SUBPART C — LABELING REQUIREMENTS FOR OVER-THE-COUNTER DRUGS

§ 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

(a) Scope. This section sets forth the content and format requirements for the labeling of all OTC drug products. Where an OTC drug product is the subject of an applicable monograph or regulation that contains content and format requirements that conflict with this section, the content and format requirements in this section must be followed unless otherwise specifically provided in the applicable monograph or regulation.

(b) Definitions. The following definitions apply to this section:

(1) Act means the Federal Food, Drug, and Cosmetic Act (secs. 201 et seq. (21 U.S.C. 321 et seq.)).

(2) Active ingredient means any component that is intended to furnish pharmacological activity

or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(3) Approved drug application means a new drug (NDA) or abbreviated new drug (ANDA) application approved under section 505 of the act (21 U.S.C. 355).

(4) Bullet means a geometric symbol that precedes each statement in a list of statements. For purposes of this section, the bullet style is limited to solid squares or solid circles, in the format set forth in paragraph (d)(4) of this section.

(5) Established name of a drug or ingredient thereof means the applicable official name designated under section 508 of the act (21 U.S.C. 358), or, if there is no designated official name and the drug or ingredient is recognized in an official compendium, the official title of the drug or ingredient in such compendium, or, if there is no designated official name and the drug or ingredient is not recognized in an official compendium, the common or usual name of the drug or ingredient.

(6) FDA means the Food and Drug Administration.

(7) Heading means the required statements in quotation marks listed in paragraphs (c)(2) through (c)(9) of this section, excluding subheadings (as defined in paragraph (a)(9) of this section).

(8) Inactive ingredient means any component other than an active ingredient.

(9) Subheading means the required statements in quotation marks listed in paragraphs (c)(5)(ii) through (c)(5)(vii) of this section.

(10) Drug facts labeling means the title, headings, subheadings, and information required under or otherwise described in paragraph (c) of this section.

(11) Title means the heading listed at the top of the required OTC drug product labeling, as set forth in paragraph (c)(1) of this section.

(12) Total surface area available to bear labeling means all surfaces of the outside container of the retail package or, if there is no such outside container, all surfaces of the immediate container or container wrapper except for the flanges at the tops and bottoms of cans and the shoulders and necks of bottles and jars.

(c) Content requirements. The outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper, shall contain

the title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(8) of this section, and may contain the information under the heading in paragraph (c)(9) of this section, in the order listed.

(1) (Title) "Drug Facts". If the drug facts labeling appears on more than one panel, the title "Drug Facts (continued)" shall appear at the top of each subsequent panel containing such information.

(2) "Active ingredient" or "Active ingredients" "(in each [insert the dosage unit stated in the directions for use (e.g., tablet, 5 mL teaspoonful) or in each gram as stated in §§ 333.110 and 333.120 of this chapter])", followed by the established name of each active ingredient and the quantity of each active ingredient per dosage unit. Unless otherwise provided in an applicable OTC drug monograph or approved drug application, products marketed without discrete dosage units (e.g., topicals) shall state the proportion (rather than the quantity) of each active ingredient.

(3) "Purpose" or "Purposes", followed by the general pharmacological category(ies) or the principal intended action(s) of the drug or, where the drug consists of more than one ingredient, the general pharmacological categories or the principal intended actions of each active ingredient. When an OTC drug monograph contains a statement of identity, the pharmacological action described in the statement of identity shall also be stated as the purpose of the active ingredient.

(4) "Use" or "Uses", followed by the indication(s) for the specific drug product.

(5) "Warning" or "Warnings", followed by one or more of the following, if applicable:

(i) "For external use only" [in bold type] for topical drug products not intended for ingestion, or "For" (select one of the following, as appropriate: "rectal" or "vaginal") "use only" [in bold type].

(ii) All applicable warnings listed in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section with the appropriate subheadings highlighted in bold type:

(A) Reye's syndrome warning for drug products containing salicylates set forth in § 201.314(h)(1). This warning shall follow the subheading "Reye's syndrome:"

(B) Allergic reaction warnings set forth in any applicable OTC drug monograph or approved drug application for any product that requires a separate allergy warning. This warning shall follow the subheading "Allergy alert:"

(C) Flammability warning, with appropriate flammability signal word (e.g., §§ 358.150(c) and 358.550(c) of this chapter). This warning shall follow a subheading containing the appropriate flammability signal word described in an applicable OTC drug monograph or approved drug application.

(D) Water soluble gums warning set forth in § 201.319. This warning shall follow the subheading "Choking:"

(E) Alcohol warning set forth in § 201.322. This warning shall follow the subheading "Alcohol warning:"

(F) Sore throat warning set forth in § 201.315. This warning shall follow the subheading "Sore throat warning:"

(G) Warning for drug products containing sodium phosphates set forth in § 201.307(b)(2)(i) or (b)(2)(ii). This warning shall follow the subheading "Dosage warning:"

(iii) "Do not use" [in bold type], followed by all contraindications for use with the product. These contraindications are absolute and are intended for situations in which consumers should not use the product unless a prior diagnosis has been established by a doctor or for situations in which certain consumers should not use the product under any circumstances regardless of whether a doctor or health professional is consulted.

(iv) "Ask a doctor before use if you have" [in bold type] or, for products labeled only for use in children under 12 years of age, "Ask a doctor before use if the child has" [in bold type], followed by all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until a doctor is consulted.

(v) "Ask a doctor or pharmacist before use if you are" [in bold type] or, for products labeled only for use in children under 12 years of age, "Ask a doctor or pharmacist before use if the child is" [in bold type], followed by all drug-drug and drug-food interaction warnings.

(vi) "When using this product" [in bold type], followed by the side effects that the consumer may experience, and the substances (e.g., alcohol) or activities (e.g., operating machinery, driving a car, warnings set forth in § 369.21 of this chapter for drugs in dispensers pressurized by gaseous propellants) to avoid while using the product.

(vii) "Stop use and ask a doctor if" [in bold type], followed by any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product.

(viii) Any required warnings in an applicable OTC drug monograph, other OTC drug regulations, or approved drug application that do not fit within one of the categories listed in paragraphs (c)(5)(i) through (c)(5)(vii), (c)(5)(ix), and (c)(5)(x) of this section.

(ix) The pregnancy/breast-feeding warning set forth in § 201.63(a); the third trimester warning set forth in § 201.63(e) for products containing aspirin or carbaspirin calcium; the third trimester warning set forth in approved drug applications for products containing ketoprofen, naproxen sodium, and ibuprofen

(not intended exclusively for use in children).

(x) The "Keep out of reach of children" warning and the accidental overdose/ ingestion warning set forth in § 330.1(g) of this chapter.

(6) "Directions", followed by the directions for use described in an applicable OTC drug monograph or approved drug application.

(7) "Other information", followed by additional information that is not included under paragraphs (c)(2) through (c)(6), (c)(8), and (c)(9) of this section, but which is required by or is made optional under an applicable OTC drug monograph, other OTC drug regulation, or is included in the labeling of an approved drug application.

(i) Required information about certain ingredients in OTC drug products (e.g., sodium in § 201.64(c)) shall appear as follows: "each (insert appropriate dosage unit) contains:" [in bold type] (insert name(s) of ingredient(s) and the quantity of each ingredient). This information shall be the first statement under this heading.

(ii) The phenylalanine/aspartame content required by § 201.21(b), if applicable, shall appear as the next item of information.

(iii) Additional information that is authorized to appear under this heading shall appear as the next item(s) of information. There is no required order for this subsequent information.

(8) "Inactive ingredients", followed by a listing of the established name of each inactive ingredient. If the product is an OTC drug product that is not also a cosmetic product, then the inactive ingredients shall be listed in alphabetical order. If the product is an OTC drug product that is also a cosmetic product, then the inactive ingredients shall be listed as set forth in § 701.3(a) or (f) of this chapter, the names of cosmetic ingredients shall be determined in accordance with § 701.3(c) of this chapter, and the provisions in § 701.3(e), (g), (h), (l), (m), (n), and (o) of this chapter and § 720.8 of this chapter may also apply, as appropriate. If there is a difference in the labeling provisions in this § 201.66 and §§ 701.3 and 720.8 of this chapter, the labeling provisions in this § 201.66 shall be used.

(9) "Questions?" or "Questions or comments?", followed by the telephone number of a source to answer questions about the product. It is recommended that the days of the week and times of the day when a person is available to respond to questions also be included. A graphic of a telephone or telephone receiver may appear before the heading. The telephone number must appear in a minimum 6-point bold type.

(d) Format requirements. The title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(9) of this section shall be presented on OTC drug products in accordance with the following specifications. In the interest of uniformity of presentation, FDA strongly recommends that the Drug Facts labeling be presented using the graphic specifications set forth in appendix A to part 201.

(1) The title "Drug Facts" or "Drug Facts (continued)" shall use uppercase letters for the first letter of the words "Drug" and "Facts." All headings and subheadings in paragraphs (c)(2) through (c)(9) of this section shall use an uppercase letter for the first letter in the first word and lowercase letters for all other words. The title, headings, and subheadings in paragraphs (c)(1), (c)(2), and (c)(4) through (c)(9) of this section shall be left justified.

(2) The letter height or type size for the title "Drug Facts" shall appear in a type size larger than the largest type size used in the Drug Facts labeling. The letter height or type size for the title "Drug Facts (continued)" shall be no smaller than 8-point type. The letter height or type size for the headings in paragraphs (c)(2) through (c)(9) of this section shall be the larger of either 8-point or greater type, or 2-point sizes greater than the point size of the text. The letter height or type size for the subheadings and all other information described in paragraphs (c)(2) through (c)(9) of this section shall be no smaller than 6-point type.

(3) The title, heading, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section shall be legible and clearly presented, shall have at least 0.5-point leading (i.e., space between two lines of text), and shall not have letters that touch. The type style for the title, headings, subheadings, and all other required information described in paragraphs (c)(2) through (c)(9) of this section shall be any single, clear, easy-to-read type style, with no more than 39 characters per inch. The title and headings shall be in bold italic, and the subheadings shall be in bold type, except that the word "(continued)" in the title "Drug Facts (continued)" shall be regular type. The type shall be all black or one color printed on a white or other contrasting background, except that the title and the headings may be presented in a single, alternative, contrasting color unless otherwise provided in an approved drug application, OTC drug monograph (e.g., current requirements for bold print in §§ 341.76 and 341.80 of this chapter), or other OTC drug regulation (e.g., the requirement for a box and red letters in § 201.308(c)(1)).

(4) When there is more than one statement, each individual statement listed under the headings and subheadings in paragraphs (c)(4) through (c)(7) of this section shall be preceded by a solid square or solid circle bullet of 5-point type size. Bullets shall be presented in the same shape and color throughout the labeling. The first bulleted statement on each horizontal line of text shall be either left justified or

separated from an appropriate heading or subheading by at least two square "ems" (i.e., two squares of the size of the letter "M"). If more than one bulleted statement is placed on the same horizontal line, the end of one bulleted statement shall be separated from the beginning of the next bulleted statement by at least two square "ems" and the complete additional bulleted statement(s) shall not continue to the next line of text. Additional bulleted statements appearing on each subsequent horizontal line of text under a heading or subheading shall be vertically aligned with the bulleted statements appearing on the previous line.

(5) The title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(9) of this section may appear on more than one panel on the outside container of the retail package, or the immediate container label if there is no outside container or wrapper. The continuation of the required content and format onto multiple panels must retain the required order and flow of headings, subheadings, and information. A visual graphic (e.g., an arrow) shall be used to signal the continuation of the Drug Facts labeling to the next adjacent panel.

(6) The heading and information required under paragraph (c)(2) of this section shall appear immediately adjacent and to the left of the heading and information required under paragraph (c)(3) of this section. The active ingredients and purposes shall be aligned under the appropriate headings such

that the heading and information required under paragraph (c)(2) of this section shall be left justified and the heading and information required under paragraph (c)(3) of this section shall be right justified. If the OTC drug product contains more than one active ingredient, the active ingredients shall be listed in alphabetical order. If more than one active ingredient has the same purpose, the purpose need not be repeated for each active ingredient, provided the information is presented in a manner that readily associates each active ingredient with its purpose (i.e., through the use of brackets, dot leaders, or other graphical features). The information described in paragraphs (c)(4) and (c)(6) through (c)(9) of this section may start on the same line as the required headings. None of the information described in paragraph (c)(5) of this section shall appear on the same line as the "Warning" or "Warnings" heading.

(7) Graphical images (e.g., the UPC symbol) and information not described in paragraphs (c)(1) through (c)(9) of this section shall not appear in or in any way interrupt the required title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section. Hyphens shall not be used except to punctuate compound words.

(8) The information described in paragraphs (c)(1) through (c)(9) of this section shall be set off in a box or similar enclosure by the use of a barline. A distinctive horizontal barline extending to each

end of the "Drug Facts" box or similar enclosure shall provide separation between each of the headings listed in paragraphs (c)(2) through (c)(9) of this section. When a heading listed in paragraphs (c)(2) through (c)(9) of this section appears on a subsequent panel immediately after the "Drug Facts (continued)" title, a horizontal hairline shall follow the title and immediately precede the heading. A horizontal hairline extending within two spaces on either side of the "Drug Facts" box or similar enclosure shall immediately follow the title and shall immediately precede each of the subheadings set forth in paragraph (c)(5) of this section, except the subheadings in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section.

(9) The information set forth in paragraph (c)(6) of this section under the heading "Directions" shall appear in a table format when dosage directions are provided for three or more age groups or populations. The last line of the table may be the horizontal barline immediately preceding the heading of the next section of the labeling.

(10) If the title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section, printed in accordance with the specifications in paragraphs (d)(1) through (d)(9) of this section, and any other FDA required information for drug products, and, as appropriate, cosmetic products, other than information required to appear on a principle display panel, requires more than

60 percent of the total surface area available to bear labeling, then the Drug Facts labeling shall be printed in accordance with the specifications set forth in paragraphs (d)(10)(i) through (d)(10)(v) of this section. In determining whether more than 60 percent of the total surface area available to bear labeling is required, the indications for use listed under the "Use(s)" heading, as set forth in paragraph (c)(4) of this section, shall be limited to the minimum required uses reflected in the applicable monograph, as provided in § 330.1(c)(2) of this chapter.

(i) Paragraphs (d)(1), (d)(5), (d)(6), and (d)(7) of this section shall apply.

(ii) Paragraph (d)(2) of this section shall apply except that the letter height or type size for the title "Drug Facts (continued)" shall be no smaller than 7-point type and the headings in paragraphs (c)(2) through (c)(9) of this section shall be the larger of either 7-point or greater type, or 1-point size greater than the point size of the text.

(iii) Paragraph (d)(3) of this section shall apply except that less than 0.5-point leading may be used, provided the ascenders and descenders do not touch.

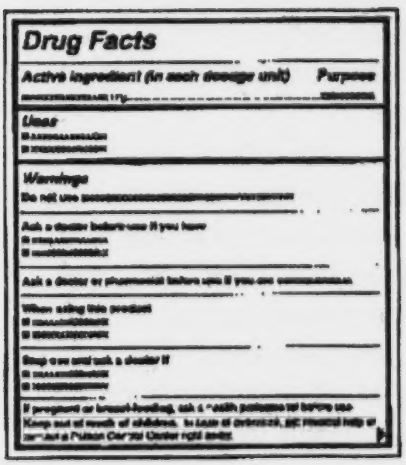
(iv) Paragraph (d)(4) of this section shall apply except that if more than one

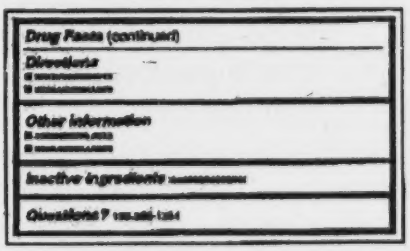
bulleted statement is placed on the same horizontal line, the additional bulleted statements may continue to the next line of text, and except that the bullets under each heading or subheading need not be vertically aligned.

(v) Paragraph (d)(8) of this section shall apply except that the box or similar enclosure required in paragraph (d)(8) of this section may be omitted if the Drug Facts labeling is set off from the rest of the labeling by use of color contrast.

(11)(i) The following labeling outlines the various provisions in paragraphs (c) and (d) of this section:

OTC Drug Product Labeling Outline

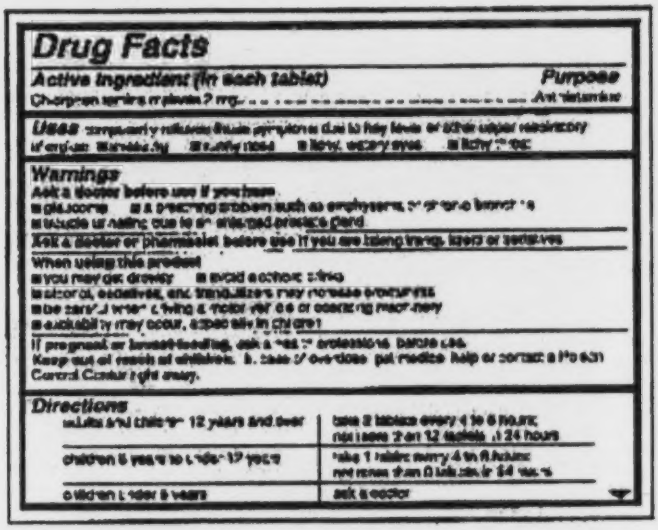




BEST AVAIL

Appendix H

(ii) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section:



Drug Facts

Active ingredient (in each tablet) **Purpose**

Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis

■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

■ you may get drowsy ■ avoid alcoholic drinks

■ alcohol, sedatives, and tranquilizers may increase drowsiness

■ be careful when driving a motor vehicle or operating machinery

■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

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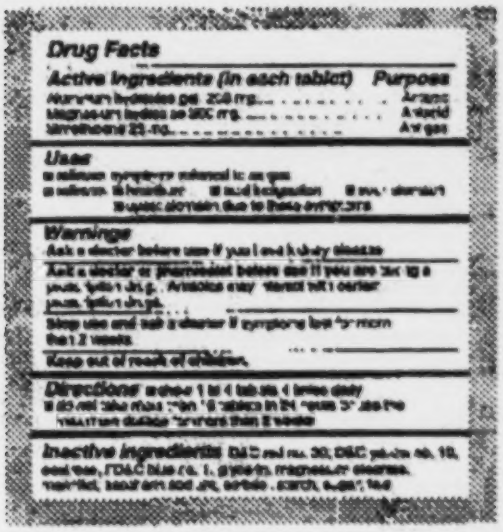
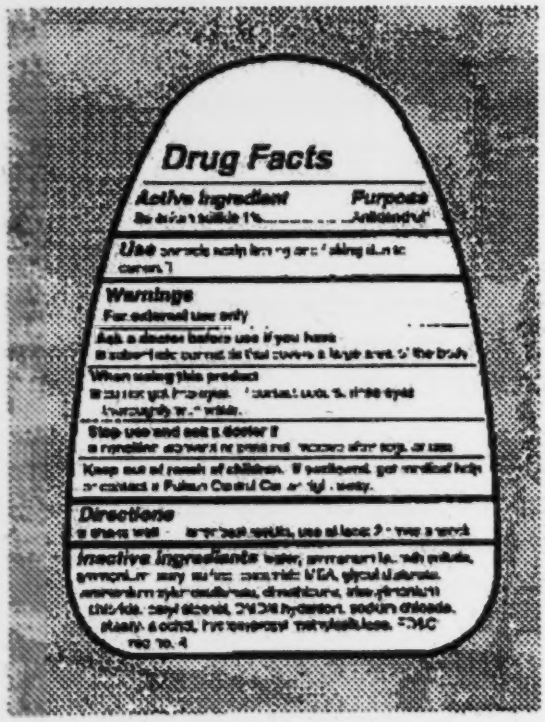
Appendix H

(iii) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section, including paragraph (d)(10) of this section, which permits modifications for small packages:



Appendix H

(iv) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section for a drug product marketed with cosmetic claims:



(e) Exemptions and deferrals. FDA on its own initiative or in response to a written request from any manufacturer, packer, or distributor, may exempt or defer, based on the circumstances presented, one or more specific requirements set forth in this section on the basis that the requirement is inapplicable, impracticable, or contrary to public health or safety. Requests for exemptions shall be submitted in three copies in the form of an "Application for Exemption" to the

Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The request shall be clearly identified on the envelope as a "Request for Exemption from 21 CFR 201.66 (OTC Labeling Format)" and shall be directed to Docket No. 98N-0337. A separate request shall be submitted for each OTC drug product. Sponsors of a product marketed under an approved drug application shall also submit a single copy of the exemption request to their application. Decisions on exemptions and deferrals will be maintained in a permanent file in this docket for public review. Exemption and deferral requests shall:

(1) Document why a particular requirement is inapplicable, impracticable, or is contrary to public health or safety; and

(2) Include a representation of the proposed labeling, including any outserts, panel extensions, or other graphical or packaging techniques intended to be used with the product.

(f) Interchangeable terms and connecting terms. The terms listed in § 330.1(i) of this chapter may be used interchangeably in the labeling of OTC drug products, provided such use does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by regulation. The terms listed in § 330.1(j) of this chapter may be deleted from the labeling of OTC drug products when the labeling is revised to comply with this section, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by

regulation. The terms listed in § 330.1(i) and (j) of this chapter shall not be used to change in any way the specific title, headings, and subheadings required under paragraphs (c)(1) through (c)(9) of this section.

(g) Regulatory action. An OTC drug product that is not in compliance with the format and content requirements in this section is subject to regulatory action.

[64 FR 13286, March 17, 1999; 64 FR 18571, April 15, 1999; 65 FR 8, Jan. 3, 2000]